The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law

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The development of substantive patent law is principally associated with the United States Court of Appeals for the Federal Circuit (Federal Circuit). The Patent and Trademark Office (PTO), the central agency in the patent system, is largely thought to play a negligible role in the evolution of substantive patent law standards. This Article challenges this view and argues that the PTO has a considerable effect on the development of substantive standards—one that drives substantive patent law in an expansive direction. It begins by focusing on the PTO's inevitable need to develop its own views on substantive patent law. It then identifies and explains how key elements of the administrative structure of the Agency, as well as its relationship with the Federal Circuit, generally push the PTO's views on substantive patent law in a patent-protection direction. Significantly, this Article also explores how the PTO's tendency to expand the patentability standards, in turn, creates pressure on the Federal Circuit to enunciate legal standards that are expansive in nature. Finally, it examines multiple mechanisms which could improve the PTO's ability to develop substantive patent law.

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I. INTRODUCTION

The United States Court of Appeals for the Federal Circuit (Federal Circuit) has been recognized as "perhaps the single most significant institutional innovation in the field of intellectual property in the last quarter-century."[1] The Federal Circuit, which is vested with near exclusive jurisdiction over patent appeals, was created in 1982 in large part to bring uniformity to the application and development of patent law.[2] While the standards of patentability are defined by statute,[3] they are only skeletal in

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[1] WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 7 (2003).

[2] *See* Lawrence Baum, *Specializing the Federal Courts: Neutral Reforms or Efforts to Shape Judicial Policy?*, 74 JUDICATURE 217, 223 (1991); Harold H. Bruff, *Specialized Courts in Administrative Law*, 43 ADMIN. L. REV. 329, 330 (1991); Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 7 (1989).

[3] Patents may issue for "any new and useful process, machine, manufacture, or composition of matter," 35 U.S.C. § 101 (2006), that is not "obvious at the time the invention was made to a person having ordinary skill in the art," *id.* § 103, and that is described "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . . ." *Id.* § 112.

structure.[4] The Patent Act thus demands legal interpretation to infuse it with any practical meaning. The Federal Circuit is widely recognized as playing a salient role in the development of substantive patent law.[5] It is generally agreed that the appellate court has increased legal uniformity and predictability,[6] but there is disagreement as to whether the appellate court has been successful in improving the quality of patent law.[7]

One of the chief complaints against the Federal Circuit is its adoption of overly permissive patentability standards and its dramatic expansion of the scope of patentable subject matter.[8] Substantive patent law standards are critical to ensuring that the underlying goal of the patent system—promoting innovation—is well-served.[9] While patents promote innovation by giving a time-limited exclusive right in order to induce investment in new inventions, patents also impose significant costs on consumers and innovators—higher

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[4] *See* Craig Allen Nard, *Legal Forms and the Common Law of Patents*, 90 B.U. L. REV. 51, 53 (2010) ("[T]he patent code, much like the Sherman Act, is a common law enabling statute, leaving ample room for courts to fill in the interstices or to create doctrine emanating solely from Article III's province."); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1041 (2003) ("[T]he history of the patent statute as well as its language strongly suggest that Congress has delegated policymaking responsibility in patent law to the judiciary.").

[5] John M. Golden, *The Supreme Court as "Prime Percolator": A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. REV. 657, 665 (2009) ("[T]he Federal Circuit generally provides the last word on interpretive questions in substantive patent law.").

[6] *E.g.*, Dreyfuss, *supra* note 2, at 8.

[7] Uniformity and quality are distinct attributes. *See* Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity Principle*, 101 NW. U. L. REV. 1619, 1620 (2007) (arguing that "uniformity is not a proxy for quality" and outlining a number of critiques of the Federal Circuit's patent law jurisprudence).

[8] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 5–6 (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (arguing that the Federal Circuit's nonobviousness standards are too low and allow for excessive patenting); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 36–37 (2004); Rai, *supra* note 4, at 1054 (arguing that the Federal Circuit's application of the nonobviousness standard to DNA sequences results in over-patenting of DNA sequences); *see also* Jay Dratler, Jr., *Alice in Wonderland Meets the U.S. Patent System*, 38 AKRON L. REV. 299, 300 (2005) (arguing that the Federal Circuit has unjustifiably enlarged the scope of patentable subject matter); Michael North, *The U.S. Expansion of Patentable Subject Matter: Creating a Competitive Advantage for Foreign Multinational Companies?*, 18 B.U. INT'L L.J. 111, 138 (2000) (same); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1140–41 (1999) (same).

[9] *See* U.S. CONST. art. I, § 8, cl. 8.

prices and less access to the invention during the duration of the patent.[10] If the patentability standards become too expansive then the costs of patents may cease to outweigh the benefits to consumers. For example, overly broad patentability standards that result in the patenting of inventions that either would have been developed without a patent or result in the issuance of patents on inventions that are already in the public domain likely decrease overall social welfare.[11]

To date, scholars have provided a number of explanations for the Federal Circuit's unwarranted expansion of the patentability standards; including the appellate court's capture by the patent bar and its clients[12] and a lack of scientific expertise.[13] This Article offers a novel explanation—one that begins with recognition of the United States Patent and Trademark Office (PTO) as an important institutional actor in the development of patent law. In contrast to the Federal Circuit, the role the PTO has played in the setting and the recent expansion of patentability standards has received scant

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[10] *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 6 (1998); Michael Abramowicz, *The Uneasy Case for Patent Races Over Auctions*, 60 STAN. L. REV. 803, 809–10 (2007) (assessing whether patent auctions can be structured to benefit the social welfare).

[11] *See generally* Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non-Injunctive Remedies*, 97 MICH. L. REV. 985, 1018–20 (1999); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101 (2006).

[12] LANDES & POSNER, *supra* note 1, at 335 (arguing that, as predicted, the Federal Circuit would become a pro-patent court due, at least in part, to special interest groups including "the patent bar and its clients," who "would exert themselves to influence" judicial selection for the court); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 251 (1998) (concluding that findings of patent validity have been significantly higher since the establishment of the Federal Circuit); Rai, *supra* note 4, at 1110–11 (discussing that Federal Circuit decisions can be explained, in part, by capture). *But see* Golden, *supra* note 5, at 685–86 (dismissing arguments that the Federal Circuit has been captured); Glynn S. Lunney, Jr., *Patent Law, the Federal Circuit, and the Supreme Court: A Quiet Revolution*, 11 SUP. CT. ECON. REV. 1, 3 (2004) ("Despite the Federal Circuit's pro-patent holder reputation, this summary reveals that claims of patent infringement are no more likely to succeed since the Federal Circuit's advent.").

[13] ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 299–327 (4th ed. 2007) (describing the Federal Circuit's struggles with the written description requirement); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833–35 (1999) (arguing that the Federal Circuit's categorization of DNA-based technology as "just another species of chemistry" is flawed and has led to overly permissive application of the nonobviousness standard to DNA sequences);

scholarly attention. The PTO lacks substantive rulemaking authority,[14] and although it is statutorily authorized to adjudicate adverse decisions by patent examiners,[15] the Federal Circuit does not give any formal deference to these legal determinations.[16] Largely due to this lack of formal deference, it has been widely believed that the Agency plays a trivial role in substantive patent law development.[17] In fact, much of the existing literature fails to fully appreciate the extent of the Agency's engagement in interpreting and developing its own views of substantive patent law. Yet, a description of patent law that focuses almost exclusively on the Federal Circuit is misleading. Not only does the current literature largely ignore one of the richest sources of patent law, Agency level biases that are most likely to manifest in the PTO's announcement of its legal views have not been fully explored.[18]

Recent scholarship has begun to provide a more nuanced analysis of the PTO's influence on the evolution of legal standards. Clarisa Long notes that the PTO has emerged as a "more robust institutional player actively seeking to influence patent policy"[19] by successfully lobbying for the passage of legislation that empowered the Agency with more control over its operations,[20] convincing the Supreme Court that its factual findings deserved a more deferential standard of review than the Federal Circuit had been

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[14] *See* Merck & Co. v. Kessler, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996) (stating that because the Patent Act "does [not] grant the Commissioner the authority to issue substantive rules . . . the rule of controlling deference set forth in *Chevron* does not apply").

[15] 35 U.S.C. § 6(b) (2006).

[16] Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269, 299 (2007) ("[T]he Federal Circuit has repeatedly stated that it grants no deference whatsoever to PTO legal interpretations.").

[17] *See, e.g.*, Golden, *supra* note 5, at 665 (noting that the Federal Circuit faces little competition from the PTO in developing substantive patent law); Jonathan Masur, *Patent Inflation* 1 (U. of Chi. Pub. Law, Working Paper No. 316, 2010), *available at* http://ssrn.com/abstract=1623929 ("The Federal Circuit dictates the rules of substantive patent law to the patent office via interpretations of the Patent Act. The PTO then grants or denies patents according to those rules."); Nard, *supra* note 4, at 76 (describing the PTO's role in substantive patent law as minor).

[18] This is in contrast to examiner biases that have been discussed at length in the literature. *See infra* Part IV.

[19] Clarisa Long, *The PTO and the Market for Influence in Patent Law*, 157 U. PA. L. REV. 1965, 1966 (2009).

[20] *Id.* at 1974–75.

applying,[21] and testing the scope of its procedural rulemaking.[22] As a result of these three events, she says, the PTO today enjoys an increased role as a "supplier of legal rules and patent polices."[23] Yet she maintains the Federal Circuit's dominance in substantive patent law, noting that the appellate court "has been the major force affecting the shape of patent law . . . ."[24]

Jeffrey Lefstin argues that lack of explicit policy in current Federal Circuit patent jurisprudence derives in large part from the Federal Circuit's predecessor court, the Court of Customs and Patent Appeals (CCPA), and its unique relationship with the PTO.[25] He contends that because the PTO's interaction with a patent almost always ends upon its issuance, the Agency has a limited ability to understand the consequences of granting a patent under a particular legal rule and thus the Agency's views on substantive patent law are not informed by long-range policy considerations.[26] Because the CCPA's patent jurisdiction was limited to only patentability decisions by the PTO, he argues that the court's views on substantive law suffered from the same shortcomings of the PTO's.[27] According to Lefstin, the Federal Circuit's adoption of CCPA case law as controlling precedent set the contours of the appellate court's policy-deprived patent jurisprudence.[28]

Thus, scholars have begun to explore the PTO's role in shaping the contours of substantive law. This exploration, however, is far from complete. Along this vein, this Article argues that the PTO plays an important role in and has a strong practical effect on the evolution of substantive patent law standards—one that generally pushes substantive patent law in an expansive direction. Thus, this Article makes two primary contributions. First, it argues that the PTO plays a much larger role in shaping substantive patent law standards than is generally recognized in the patent law literature. Second, it

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[21] *Id.* at 1975–77. In *Dickson v. Zurko*, 527 U.S. 150, 153–54, 165 (1999), the Court held that the Administrative Procedure Act's more deferential "substantial evidence" or "arbitrary and capricious" standards of review applied to the PTO's factual findings when patent applicants appeal directly to the Federal Circuit. Prior to *Zurko*, the Federal Circuit was applying the "clearly erroneous" standard of review to the PTO's factual conclusion.

[22] Long, *supra* note 19, at 1979–83.

[23] *Id.* at 1973–74.

[24] *Id.* at 1971.

[25] Jeffrey A. Lefstin, *The Constitution of Patent Law: The Court of Customs and Patent Appeals and the Shape of the Federal Circuit's Jurisprudence*, 43 LOY. L.A. L. REV. 843, 847 (2010) ("The Federal Circuit was created by the merger of the Court of Customs and Patent Appeals (CCPA) and the appellate division of the Court of Claims.").

[26] *Id.* at 853.

[27] *Id.* at 853–54.

[28] *Id.* at 885.

provides an explanation for the expansion of patentability standards that focuses on agency level incentives of the PTO.

This Article proceeds in five parts. Part II of this Article argues that the PTO is a much more vibrant actor in setting substantive patent standards than is generally recognized in the literature. Even though the Agency must follow court precedent and the Patent Act in making patentability decisions, these legal instruments often fail to dictate the outcome of patentability decisions to the Agency. The PTO routinely develops its own views of substantive law in order to fill legal voids, largely in an effort to give guidance to its examiners and patent applicants. Part II delineates why and where PTO discretion with respect to substantive law exists, details the mechanism the Agency utilizes to develop and articulate its own views of substantive law, and begins to explore how the Agency has a strong practical effect on setting substantive standards.

Because scholars have not focused on the PTO as a source of patent law, the existing literature does not fully explore how the institutional design of the PTO and its relationship with the Federal Circuit affect the Agency's official positions on substantive law. Part III of this Article identifies and explains how both the asymmetric review of PTO determinations and the Agency's asymmetric funding generally push the PTO's views on substantive patent law in a patent-protective direction. Unlike most administrative agencies, substantive determinations by the PTO are not subject to symmetric review by the Judiciary. It is only when the PTO denies a patent that its decision may be immediately reviewed by the Federal Circuit. In contrast, when the PTO grants a patent, its actions will go uncontested for many years, if contested at all. Because the PTO seeks to minimize scrutiny of its decision making, as well as its chances for reversal, the asymmetric review of PTO decisions results in an institutional tendency to expand substantive law.[29]

The asymmetric funding of the Agency largely reinforces this bias in substantive decision making. The PTO is funded entirely through user fees; the PTO's budget is set to the amount of its projected revenue. As a result, the PTO's patent operating budget is derived, in large part, from patent examination and post-allowance fees. However, the fees the PTO collects for examining patent applications covers less than one-third of the cost to the Agency for performing this service. In contrast, the post-allowance fees—fees the Agency only collects when it grants a patent—are pure profit, as it costs the Agency next to nothing to perform these services. Thus, the PTO's

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[29] Jonathan Masur, working independently, has recently explored the effect of unidirectional review of PTO decisions and has largely reached the same conclusion. Masur, *supra* note 17, at 2.

strong funding incentives to grant patents also results in a systematic driving force, shaping the Agency's views on substantive law in the patent-protective direction.

Recognizing that the asymmetric incentives explored in Part III are likely to be internalized by high-level officials at the PTO, Part IV begins to examine the incentive structure of patent examiners. While the Agency uses guidance documents and its own internal board to provide examiners with the PTO's views on substantive law, there are other channels that high-ranking officials may utilize to exert expansionary pressure on patent law. This Part explores one such channel—the incentives of patent examiners. A number of scholars have noted that patent examiner incentives are tilted towards allowances.[30] This Part provides a possible explanation for why the Agency has chosen to structure examiner incentives in this manner.

In theory, the Federal Circuit could always rein in the expansive substantive standards being applied by the PTO. Part V explores two mechanisms, resulting from the PTO's overly permissive views of substantive law, which create pressure for the Federal Circuit to enunciate legal standards that drift in the expansive direction. First, once the PTO begins making decisions on the patentability of inventions based on a substantive standard that is too expansive, a susceptibility to lock-in may arise, especially if the Federal Circuit is not given, in a timely manner, the opportunity to consider whether the PTO's stance is desirable. Second, the PTO's patent-protective views of substantive law skew the distribution of patent denials before the Federal Circuit; the overwhelming majority of patents denied by the PTO are likely to be invalid. Part V also examines how this skewed distribution of cases may affect the evaluative and decisional process of the Federal Circuit.

Finally, Part VI explores various policies that Congress could adopt to either temper or eliminate the distortions to substantive patent law development caused by both the asymmetric review of the Agency's determinations and the PTO's financial incentives to grant patents. To balance the review of PTO determinations, Part VI recommends enacting an administrative proceeding whereby granted patents can be challenged by third parties. To address the distortions caused by the PTO's financial incentives to grant patents, Part VI considers both abolishing the disparity between examination fees and costs to the PTO, and funding the Agency, at least partially, through direct appropriations. As the aligning of fees and costs in the examination process will likely leave the Agency with a continued incentive to grant patents—the majority of the PTO's budget will still be

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[30] *See infra* notes 147–49.

derived through post-allowance fees—Part VI ultimately recommends eliminating, at least partially, the self-financing of the PTO.

II. THE PTO'S UNDERAPPRECIATED ROLE IN SETTING SUBSTANTIVE STANDARDS

Since 1790, Congress has provided a system for granting patents, including the basic patentability requirements.[31] However, up to this point, the implementing legislation leaves ample room for gap-filling and interpretation.[32] It is widely recognized that the Judiciary, and in particular the Federal Circuit, which has near exclusive jurisdiction over patent appeals, has played a salient role in filling this legal void.[33]

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[31] The first patent act gave the Secretary of State, the Secretary of War, and the Attorney General the authority to examine and issue patents. *See* Patent Act of 1790, ch. 7, § 1, 1 Stat. 109, 109–10 (1790). It was the Patent Act of 1836, however, that created the PTO and vested it with the authority to administer the patent system. *See* Patent Act of 1836, ch. 357, § 1, 5 Stat. 117, 117–18 (1836); *see also* Patent Act of 1952, Pub. L. No. 82-593, 66 Stat. 792 (codified at 35 U.S.C. §§ 100–376) (2006).

[32] *See* Hon. Timothy B. Dyk, *Does the Supreme Court Still Matter?*, 57 AM. U. L. REV. 763, 766 (2008) ("Since the very beginning of our nation, Congress has provided a system for the granting of patents. However, up to now, the implementing legislation has not been a great deal more specific than the Constitution itself . . . .").

[33] *See, e.g.*, Nard, *supra* note 4, at 76–77; *see also* Federal Court Improvements Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (relevant provisions codified as amended in scattered sections of 28 U.S.C.); 28 U.S.C. § 1295(a)(1), (a)(4)(a) (2006). Prior to 1982, patent appeals from district courts were heard by the respective regional circuit court and appeals from PTO decisions on patentability were heard by the Court of Customs and Patent Appeals (CCPA). Thus, twelve regional circuit courts and the CCPA provided legal interpretation and development of substantive patent law. The divergence of the intermediate appellate court's patent rules from each other, *see* Baum, *supra* note 2, at 223; Dreyfuss, *supra* note 2, at 6–7, and from the rules of the PTO, Graham v. John Deere Co., 383 U.S. 1, 18 (1966) ("We have observed a notorious difference between the standards applied by the Patent Office and by the courts."), led to the creation of the Federal Circuit.

The import of the Federal Circuit to the patent system has not been lost on scholars; commentators have explored how nearly every facet of the institutional structure of the appellate court affects the quality of patent law the court announces. *See, e.g.*, Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 815 (2008) (arguing that the Federal Circuit's "tendency to emphasize precision at the expense of accuracy" stems in part from the political context in which the court was created—namely that the court was created to bring uniformity to patent law); Rochelle Dreyfuss, *Pathological Patenting: The PTO as Cause or Cure*, 104 MICH. L. REV. 1559, 1570 (2006) (book review) [hereinafter Dreyfuss, *Pathological Patenting*] (discussing how Federal Circuit judges have developed "thin skins" in part because they do not have sister courts that criticize their decision making); Golden, *supra*

In contrast to the Federal Circuit, there has been very little examination or even acknowledgment of the important role and the practical effect the PTO plays in setting substantive standards. The patent literature often concludes that the PTO plays a trivial role in influencing substantive standards because the Agency lacks substantive rulemaking authority and that its views on substantive patent law are not entitled to the highly deferential standard articulated in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[34] However, this view ignores the reality of PTO practice and the fact that the rule announced by the court may matter much less than how the PTO chooses to implement it. In fact, much of the existing literature fails to fully appreciate the extent to which the Agency is engaged in interpreting and developing its own views of substantive patent law.[35] The prevailing view of the Agency is that of a clerk's office—examiners making haphazard decisions without substantial guidance from higher-level officials.[36]

This Part argues that the PTO is a much more vibrant actor and has a much larger practical effect on substantive law development than is generally recognized. On a daily basis, the PTO must make difficult substantive patent law decisions on issues—such as the patentability of subject matter and

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note 5, at 657 (arguing that the Federal Circuit's centralized legal control of patent law results in ossification of law and suggesting increased Supreme Court involvement in substantive patent law development); Nard & Duffy, *supra* note 7, at 1625, 1632 (arguing that Federal Circuit jurisprudence lacks quality in part because it does not have an audience—other sister courts—to write to and suggesting that the D.C. Circuit should also have jurisdiction over patent appeals); Rai, *supra* note 4, at 1040 (arguing that the Federal Circuit's formalistic jurisprudence stems from the appellate court's concern with the inability of the district court and the PTO to accurately find facts).

[34] 467 U.S. 837, 842–44 (1984); *see, e.g.*, Golden, *supra* note 5, at 665 (noting that "the Federal Circuit generally provides the last word on interpretive questions in substantive patent law" because the Agency's legal determinations receive little deference); Nard, *supra* note 4, at 76 (describing the PTO's role in substantive patent law as minor); Rai, *supra* note 4, at 1053–54 (arguing that the Federal Circuit has been hesitant to give the PTO proper deference to the Agency's factual findings, let alone any formal deference to the PTO's legal decisions).

[35] *E.g.*, DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 168 (2009) (describing the PTO as having "virtually no policy staff and—at least until recently—little experience or apparent inclination to take a leadership role in setting patent policy"); Masur, *supra* note 17, at 2 ("The Federal Circuit dictates the terms of substantive patent law to the patent office, which typically abides by those terms and works to placate both the Federal Circuit and the patent applicants who come before it.").

[36] *See, e.g.*, Michael J. Meurer, *Patent Examination Priorities*, 51 WM. & MARY L. REV. 675, 704 (2009) ("Today, patent examination is fundamentally decentralized. Examiners have enormous discretion about how they perform their mission.").

standards for nonobviousness—that the Judiciary has struggled with for years.[37] In fact, the sheer volume of patentability decisions—roughly 470,000 a year[38]—suggest that courts cannot answer all (or even most) of the difficult substantive questions that confront the PTO on a day-to-day basis. Examiners are not filling this legal void in a completely random fashion. Instead, the Agency has strong incentives to provide its employees with guidance on these unsettled legal issues. Thus, the Agency routinely develops views of substantive law that are binding on its own employees. Finally, even without formal authority, the PTO is often setting de facto substantive law because many of its determinations remain unchallenged.

Subpart A explores where and why PTO discretion exists with respect to substantive law; subpart B explores the mechanisms that the PTO utilizes to articulate the Agency's official views on substantive law; and subpart C begins to examine how the PTO is, in effect, setting substantive standards, even though its legal determinations are afforded no formal deference.

A. *The PTO's Unavoidable Discretion*

Despite the PTO's obligation to follow the patent code and court precedent,[39] there are a substantial number of areas in which neither source of law dictates the outcome of a PTO decision. These areas of discretion exist in part because the PTO is required to determine the applicability of law

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[37] *See, e.g.*, BURK & LEMLEY, *supra* note 35, at 157 ("Courts have repeatedly sought to draw lines between software inventions that involved physical transformation and those that represented merely mental steps or mathematical algorithms. At each turn, those lines quickly eroded and had to be abandoned as unworkable."); Nard, *supra* note 4, at 94 ("Over the years, the courts have constructed various tests [for claims for process inventions] .... These tests have proven to be too unpredictable and unruly—the standards therein offered very little guidance to the bar and inventors.").

[38] U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2009, at 112 tbl. 1 (2010), *available at* http://www.uspto.gov/about/stratplan/ar/2009/2009annualreport.pdf [hereinafter PERFORMANCE AND ACCOUNTABILITY REPORT].

[39] Scholars have noted that, at times, administrative agencies decline to be bound by adverse circuit decisions and have termed this behavior "nonacquiescence." *See, e.g.*, Samuel Estreicher & Richard L. Reversz, *Nonacquiescence by Federal Administrative Agencies*, 98 YALE L. J. 679, 681 (1989). While the PTO has from time to time refused to follow Federal Circuit precedent, these instances have been rare. Most agencies that engage in nonacquiescence cite horizontal uniformity (treating claimants/applicants similarly at the agency level) as the primary reason for its behavior. *See id.* at 695 (Social Security Administration's stated reason for nonacquiescence); *id.* at 714 (Internal Revenue Service's stated reason for nonacquiescence). As the Federal Circuit provides uniformity to substantive patent law, the PTO lacks the primary incentive to partake in nonacquiescence.

to new technologies that the relevant lawmaker could not have anticipated; it must sometimes resolve ambiguities in statutory patent law and precedential court opinions; and it is required, at times, to fill gaps in the law.

1. *The Inevitable Mismatch Between Old Legal Rules and New Technologies*

The PTO develops its own views of substantive patent law when it determines the patentability of new technology—in particular technology that has never been addressed by precedent or the existing statutes.[40] Existing rules are not always adaptable to emerging fields of science; they cannot be applied mechanically to reach a determinate result. When inventors begin to file patent applications on these new technologies, the PTO will fill this legal void with its own interpretation and development of substantive law to bridge the gap that exists between the emerging technology and existing patent law standards.[41]

Take, for example, genomics—the science of heredity and variation in living organisms. The PTO has faced a number of challenging patentability questions with respect to this field, including genes, expressed sequence tags (fragments of genes),[42] and antibodies.[43] The Agency has provided

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[40] While the onward march of science is anticipated, the path it chooses to take is often unanticipated.

[41] There are three reasons to believe that the PTO will frequently have to develop its own views of substantive patent law in response to emergent technologies. First, technological innovation is dynamic; new fields are constantly emerging. Second, the initiative to extend patenting to an emerging technology lies, in the first instance, with inventors and commercial developers, not with Congress, the PTO, or the courts. Third, because new technology is often unforeseeable, the courts and Congress are unlikely to provide the PTO with substantial guidance in making these decisions.

[42] The PTO rejects patent applications for express sequence tags under its guidelines requiring biotechnology patents to have a utility that is "specific and substantial." Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). When these rejections were appealed to the Federal Circuit, the court not only affirmed the rejection but also blessed the PTO guidelines and essentially adopted the PTO's reasoning as its own. *See In re* Fisher, 421 F.3d 1365, 1372, 1374 (Fed. Cir. 2005) ("The [PTO]'s standards for assessing whether a claimed invention has a specific and substantial utility comport with this court's interpretation .... We agree with the [Board of Patent Appeals and Interferences] that the facts here are similar to those in *Brenner*.").

[43] *See* Enzo Biochem., Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002); *cf.* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352–53 (Fed. Cir. 2010) (en banc) (citing the PTO's 2001 guidelines in support of a statement regarding the nature of the written description requirement "when a patent claims a genus by its function or result").

examiners with substantial guidance on answering these questions,[44] including the highly controversial issue of whether genes should even be patent eligible.[45] The PTO developed its own views of substantive law when it began issuing these patents for "isolated and purified" genes over thirty years ago.[46] The Agency has also determined how to apply the patentability standards for bioinformatics—the research, development, or application of computational tools and approaches for expanding the use of biological

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[44] *See* Utility Examination Guidelines, 66 Fed. Reg. at 1098; Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112 ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) [hereinafter Written Description Guidelines].

[45] Some critics of gene patents have voiced ethical objections. *See* NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA 47–48 (2002) (arguing against the patenting of genes); JEREMY RIFKIN, THE BIOTECH CENTURY 65 (1998) (noting religious objections to the patenting of genes). Others express concerns over the proper balance between the need for commercial incentives to develop drugs for diseases and the virtues of open science. *See generally* Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUS. J. HEALTH L. & POL'Y 65, 89–90 (2002) (noting that patents on the breast cancer gene have had a negative effect on research in the field); Jon F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577 (2002) (noting that access to diagnostic tests for hereditary haemochromatosis has been inhibited by patents on HFE genes). Much of the legal debate has focused on whether genes constitute patentable subject matter or are products of nature and hence unpatentable. *See, e.g.*, Lori B. Andrews & Jordan Paradise, Essay, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. OF HEALTH POL'Y L. & ETHICS 403, 405 (2005) (arguing that patents on genes should not be granted because they do not constitute patentable subject matter); Philippe Jacobs & Geertrui Van Overwalle, *Gene Patents: A Different Approach*, 23 EUR. INTELL. PROP. REV. 505, 505 (2001) (arguing that patents should not be granted for DNA but only for downstream medical goods); *see also* Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 715 (2004) ("With respect to DNA gene patents, the doctrines of utility, nonobviousness, enablement, and written description have particularly challenged both the PTO and the courts as they have determined whether the particular features of a DNA molecule call for special application of these requirements.").

[46] *See* Mammalian Methallothionein Promoter System, U.S. Pat. No. 4,601,978 (filed Nov. 24, 1982) (issued July 22, 1986); Process for Producing Biologically Functional Molecular Chimeras, U.S. Pat. No. 4,237,224 (filed Jan. 4, 1979) (issued Dec. 2, 1980). Ever since, the patenting of genes has been surrounded in ethical and legal controversy. Isolated and purified genes are distinct from genes found in nature in that they have been extracted from their cellular environment and further processed to separate the particular segment of DNA of interest from other DNA in the genome. While isolated and purified genes have uses that are distinct from genes found in nature, isolated and purified genes still maintain their informational character—they still provide a blueprint for protein synthesis.

data—by largely treating these patent applications as computer programs.[47] Additionally, the PTO has decided to allow patents on tax strategies,[48] and has begun to decide patentability issues relating to synthetic biology, an emerging field involving engineering molecular building blocks.

2. *Gaps in the Law*

The PTO also develops its view of substantive law when it fills in gaps, and synthesizes or clarifies existing legislation and court precedent. However cognizant courts are of the need to issue opinions that clarify the law's demands for similarly situated parties, courts rarely eliminate the discretion of other bodies in applying these opinions to later cases. Thus, even when the PTO is merely implementing court precedent, the Agency plays a non-trivial part in patent law's development and practical effect.

Consider, for example, the PTO's actions in the aftermath of the Supreme Court's 1980 decision in *Diamond v. Chakrabarty*, which held that "human-made, genetically engineered bacterium" is patentable subject matter.[49] The Agency concluded that there was no subject matter bar to patenting living things outside of "a human being,"[50] and began to allow patents on plants[51] and other multicellular organisms, such as genetically altered oysters.[52] More recently, the Supreme Court case, *Bilski v. Kappos*,

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[47] The PTO has advised bioinformatics applicants to follow computer programming guidelines set forth in sections 2106.01 and 2106.02 of Manual of Patent Examining Procedure. *See infra* note 60; *see also* U.S. PATENT & TRADEMARK OFFICE, DEP'T OF COMMERCE, WRITTEN DESCRIPTION TRAINING MATERIALS 29–30 (Mar. 25, 2008), *available at* http://www.uspto.gov/web/menu/written.pdf (bioinformatics example).

[48] *See* William A. Drennan, *The Patented Loophole: How Should Congress Respond to this Judicial Invention?*, 59 FLA. L. REV. 229, 229 (2007); *see also Hearing on Issues Relating to the Patenting of Tax Advice Before the Subcomm. on Select Revenue Measures of the H. Comm. on Ways & Means*, 109th Cong. 6 (2006) (statement of James A. Toupin, General Counsel, United States Patent and Trademark Office) ("We at the USPTO recognize that the patenting of tax planning strategies has raised a number of concerns in Congress, the IRS, and the financial services community.").

[49] 447 U.S. 303, 305 (1980).

[50] *Policy Statement on the Patentability of Animals*, 1077 OFF. GAZ. PAT. & TRADEMARK OFFICE 24 (Apr. 21, 1987), *reprinted in* DONALD S. CHISUM, 9 CHISUM ON PATENTS app. 24-1 (2005) ("[T]he Patent and Trademark Office now considers nonnaturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter.").

[51] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 127 (2001) ("We hold that utility patents may be issued for plants.").

[52] *Ex parte* Allen, No. 86-1790, 2 U.S.P.Q.2d 1425, 1426 (B.P.A.I. Apr. 3, 1987) (holding that claimed polyploid oysters constitute patentable subject matter).

decided what test governs whether a claim to a process constitutes patentable subject matter.[53] The Court announced that the machine-or-transformation test—that subject matter is eligible for patent protection if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing"[54]—was not the sole test for patentability but instead only an investigational tool for determining the patentability of certain processes.[55]

Even putting aside the fact that the PTO must determine when the machine-or-transformation test is alone sufficient to reject a process claim, the PTO cannot even begin to implement this two-part test until the Agency defines what constitutes a particular machine and when a particular article is transformed into a different state or thing.[56] Further, the Court ultimately invalidated the patent in *Bilski* as an unpatentable abstract idea; the concurring opinion adroitly noted that the majority "never provides a satisfying account of what constitutes an unpatentable abstract idea."[57] The PTO fills these legal voids with its own views of substantive law, subject to additional guidance or revision of its views by the courts.[58]

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[53] 130 S. Ct. 3218 (2010).

[54] *Id.* at 3224.

[55] *Id.* at 3227.

[56] The PTO's definition of these terms can have a dramatic effect on consumer welfare and innovation. Specifically, the vitality of patents on computer implemented inventions (i.e., software patents) may be threatened depending on the PTO's stance on whether a general purpose computer qualifies as a "particular" machine within the meaning of the machine-or-transformation test. The PTO issued interim examination guidelines that made clear that for computer-implemented processes (i.e., computer-implemented software), a general-purpose computer must be disclosed to be programmed to perform the method steps. These program steps create a machine with sufficient specificity to qualify as patent eligible subject matter. *See* Memorandum from Andrew H. Hirshfeld, Acting Deputy Comm'r for Patent Examination Pol'y, U.S. Pat. & Trademark Office, to TC Directors 6 (Aug. 24, 2009), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf (laying out a rule that a general purpose computer qualifies as a "particular machine" when programmed to perform method steps, thereby allowing the patenting of computer software).

[57] *Bilski*, 130 S. Ct. at 3236 (Stevens, J., concurring).

[58] On the same day that the Supreme Court issued the *Bilski v. Kappos* decision, the PTO issued a two-page memorandum that instructed examiners on how to recalibrate subject-matter determinations in light of the decision. Memorandum from Robert W. Bahr, Acting Assoc. Comm'r for Patent Examination Pol'y, U.S. Pat. & Trademark Office, to Patent Examining Corps (June 28, 2010), *available at* http://www.uspto.gov/patents/law/exam/bilski_guidance_28jun2010.pdf. Less than thirty days later, the PTO published significantly more detailed guidelines in the *Federal Register* and solicited public comment. Interim Guidance for Determining Subject Matter

B. *Mechanisms for Developing and Articulating PTO Law*

Because scholars and policymakers have overlooked the extent to which the PTO sets its own internal law, the institutional mechanisms through which the PTO crafts and enforces its substantive patent law policies have been largely ignored. This Article attempts to fill this gap in the literature by examining how the Agency develops and articulates its views on substantive patent law. Examiners do not have total discretion in filling legal voids; high-level officials have strong incentives to provide guidance to the Agency's 6,000 patent examiners and to promote consistency in the examination process.[59] This subpart explores the Agency's two primary, non-mutually exclusive pathways to articulate and develop its own substantive patent law: guidance documents and decisions of the Board of Patent Appeals and Interferences (BPAI).

The first way that high-level officials articulate the Agency's viewpoint on substantive law issues is through guidance documents, such as general policy statements, guidelines, memoranda, and manuals. The most well-known guidance document is the massive Manual of Patent Examining Procedure (MPEP),[60] which is referred to as the "bible" of patent examination. In contrast to legislative rules, guidance documents do not appear to have the force of law and hence are exempt from the formal procedural requirements under the Administrative Procedure Act (APA).[61] Thus, the amount of public participation and transparency associated with

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Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,922 (July 27, 2010) [hereinafter *Bilski* Guidance]. These guidelines provided examiners with more guidance on when an invention was drawn to ineligible subject matter by delineating factors to take into consideration when making this determination. *Id.* at 43, 925–26.

[59] *See, e.g.*, Charles H. Koch, Jr. & David A. Koplow, *The Fourth Bite at the Apple: A Study of the Operation and Utility of the Social Security Administration's Appeals Council*, 17 FLA. ST. U. L. REV. 199, 266 (1990) ("Whether this appellate authority resides in the head of the agency or in some lesser body, the traditional scheme of administrative law generally places responsibility for generating policy at the top of the appellate pyramid.").

[60] An entire chapter is dedicated to the PTO's position on substantive patent law. U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINATION PROCEDURE § 2100 (8th ed., 8th rev., July 2010) [hereinafter MPEP].

[61] 5 U.S.C. § 553(b)(A) (2006) (requiring an agency that promulgates legislative rules to give public notice, an opportunity for comment, and the issuance of a "concise and general statement of basis and purpose"). For an excellent discussion of nonlegislative rules and why agencies may rely on them over legislative rules, see generally John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893 (2004).

guidance documents varies greatly.[62] Examination guidelines that the Agency publishes for notice and comment allow opportunity for public input and some transparency in the development process.[63] However, more often than not, the opportunity for public participation on guidance formation is very limited and the process of development is more or less a black box. The PTO appears to routinely rely on guidance documents that are not available to the public—such as internally distributed memoranda and internal training—to provide patent examiners with guidance on substantive patent law issues.[64] At least some of these rules appear to have been developed within a technology center, where more senior patent examiners and heads of the technology centers provide guidance to examiners directly. For example, it took the PTO close to twenty years before the Agency provided the public with its reasons for allowing patents on "isolated and purified" genes.[65]

The second way the PTO develops and articulates its views on substantive law is through the BPAI.[66] In order to obtain a patent, an inventor

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[62] In practice, the guidelines may include a short synopsis of how the PTO perceives the current state of the law, decision trees that the patent examiner should utilize in deciding whether an invention meets the substantive patent law at issue, and a set of detailed examples with analyses of how they either meet or fail to meet the legal requirement at issue. *See, e.g.*, Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement, 64 Fed. Reg. 71,427, 71,434–37 (Dec. 21, 1999).

[63] *See, e.g.*, DAVID J. KAPPOS, U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, SUBJECT MATTER ELIGIBILITY OF COMPUTER READABLE MEDIA (2010), *available at* http://www.uspto.gov/patents/law/notices/101_crm_20100127.pdf; *Policy Statement on the Patentability of Animals*, *supra* note 50, at app. 24-2; Written Description Guidelines, 66 Fed. Reg. at 1100–01; Utility Examination Guidelines, 66 Fed. Reg. at 1098; *Bilski* Guidance, 75 Fed. Reg. at 43,922–26.

[64] *See, e.g.*, Transcript of Public Hearing On Use of the Patent System to Protect Software-Related Inventions Before the PTO at 54 (Feb. 11, 1994) (Statement of Allen M. Lo), *available at* http://www.uspto.gov/web/offices/com/hearings/software/arlington/va_lo.html (describing the PTO's policy of nonimplemented versus implemented computer software, stating that "a lot of these guidelines are not published," and that he only has this information from being a patent examiner); Mainak H. Mehta & Diallo T. Crenshaw, *Patent Prosecution and Enforcement Tips in View of* In re Bilski, SUGHRUE MION PLLC, http://www.sughrue.com/publications/list.aspx?listType=pubs (scroll to article title at "3/27/2009") (discussing an internal PTO memorandum that encouraged examiners to apply an arguably new test for patentability that the PTO later adopted as its position in a court case before the Federal Circuit).

[65] Utility Examination Guidelines, 66 Fed. Reg. at 1095.

[66] 35 U.S.C. § 134 (2006). The Board sits in panels of three composed of a combination of the Director of the PTO, the Deputy Director, the Assistant Director, and the Administrative Patent Judges. MPEP, *supra* note 60, § 1202.

must file a patent application with the PTO, and, in a process known as patent prosecution, she must try to persuade the PTO that her invention meets the patentability standards.[67] A PTO official known as an examiner will eventually review the application and determine whether the invention merits the award of a patent. If the PTO grants a patent, the owner obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention for twenty years from the filing date of the patent.[68] If the examiner rejects the patent application for failing to meet one or more of the patentability requirements, then the patent applicant can pursue an appeal before the BPAI. The BPAI is composed of administrative patent judges (APJs)—"persons of competent legal knowledge and scientific ability"[69]—appointed by the Secretary of Commerce upon consultation with the Director of the PTO. Each APJ has a law degree, has been admitted to at least one state bar, and holds at least a bachelor's degree in science or engineering.[70] While the BPAI's primary function is the promotion of internal consistency in the examination process by finding and correcting examiner error,[71] the BPAI can also either develop or implement the PTO's views on substantive law.[72] The lawmaking function of BPAI

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[67] *See* 35 U.S.C. § 103 (2006).

[68] *Id.* § 154(a).

[69] *Id.* § 6.

[70] Vice Chief Judge James Moore, Vice Chief Judge Allen MacDonald, Judge Kenneth Hairston, & Judge Murriel Crawford, *A View Behing [sic] the Curtain: The BPAI Decision Making Process*, UNITED STATES PATENT AND TRADEMARK OFFICE LEGAL SOCIETY, http://www.usptols.org/uploads/A_View_Behind_the_Curtain__6_-UPDATE100408.pdf.

[71] There are three types of BPAI decisions: (1) precedential, (2) informative, and (3) routine. MICHAEL FLEMING, U.S. PATENT & TRADEMARK OFFICE, DEP'T OF COMMERCE, BOARD OF PATENT APPEALS AND INTERFERENCES STANDARD OPERATING PROCEDURE 2 (REVISION 7): PUBLICATION OF OPINIONS AND BINDING PRECEDENT 5–7 (2008), *available at* http://www.uspto.gov/web/offices/dcom/bpai/sop2.pdf (discussing binding precedent on the BPAI). The vast majority of BPAI decisions are labeled as routine.

[72] There are a number of reasons why the BPAI is likely to reflect the policy preferences of the Agency, including that the APJs are aware of the PTO's substantive views of patent law as the Chief Judge of the BPAI regularly participates in meetings that develop the PTO's position involving substantive patent law. In addition, the Chief Judge of the BPAI retains substantive authority over the BPAI, including designating the administrative patent judges for each panel. MICHAEL FLEMING, U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, BOARD OF PATENT APPEALS AND INTERFERENCES STANDARD OPERATING PROCEDURE 1 (REVISION 13): ASSIGNMENT OF JUDGES TO MERITS PANELS, MOTIONS PANELS, AND EXPANDED PANELS 1 (2009), *available at* http://www.uspto.gov/web/offices/dcom/bpai/sop1.pdf (discussing the Chief Administrative Patent Judge's role in the designation of merit panels). Therefore, the Chief Judge could use this ability to designate panels that will reflect the policy views of

adjudications generally takes one of two forms. First, there are cases in the common law mode that involve the application of established PTO views on substantive patent law issues to particular facts. Second, there are cases in which the BPAI uses the immediate controversy as a vehicle to announce a new viewpoint without much regard for the particular facts.[73]

To be sure, examiners could deviate from the PTO's official position on substantive law,[74] but there are many reasons to think such behavior would be unlikely: following the PTO's position is the quick and simple thing to do;[75] examiners are under enormous time constraints and are unlikely to have

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the PTO. Finally, if the BPAI decides to stray from Agency policy, the Director of the PTO can utilize his substantial supervisory role over the BPAI to influence its decisions. 35 U.S.C. § 6(a) (2006). While this authority is not absolute—the administrative patent judges are not mere "alter egos" of the Director—the Director of the PTO has the power to determine which BPAI decisions shall have binding precedential effect on the BPAI, ensuring that the Director has the power over which opinions have a lasting effect on the PTO decision making process. FLEMING, *supra* note 66, at 5–7 (discussing binding precedent on the BPAI). In addition, the Director can use his power to designate BPAI panels that "he hopes will render the decision he desires, even upon rehearing." *In re* Alappat, 33 F.3d 1526, 1535 (Fed. Cir. 1994). The Director even has the power to designate himself to sit on BPAI panels. Most recently, Director David Kappos joined a precedential BPAI opinion that clarified the BPAI standard of review of examiners' rejections. *Ex parte* Frye, No. 2009-006013, 94 U.S.P.Q.2d 1072, 1075-76, (B.P.A.I. Feb. 26, 2010), *available at* http://www.uspto.gov/ip/boards/bpai/decisions/prec/fd09006013.pdf (holding that no deference is given to positions taken by the examiner when considering an appellant's argument specifically challenging the examiner's findings); *see also Ex parte* Alappat, No. 91-1277, 23 U.S.P.Q.2d 1340, 1340 (B.P.A.I. Apr. 22, 1992) ("Before Manbeck, commissioner, Comer, deputy commission[er], Samuels, assistant commissioner, Serota, chairman, Calvert, vice chairman, and Linquist, Thomas, and Krass, examiners-in-chief."). The passage of the 1999 American Inventors Protection Act (AIPA) elevated the position of the head of the PTO from Commissioner to Director. Pub. L. No. 106-113, sec. 4713, § 3(a)(1), 113 Stat. 1501A-572–578 (1999).

[73] *Ex parte Bilski*, No. 2002-2257 (B.P.A.I. Sept. 26, 2006), *available at* http://www.uspto.gov/ip/boards/bpai/decisions/inform/fd022257.pdf, represents this type of action, though patent examiners appear to have been told beforehand to begin to reject patent applications that did not meet the PTO's machine or transformation test. *Ex parte* Allen, No. 86-1790, 2 U.S.P.Q.2d 1425 (B.P.A.I. Apr. 3, 1987) (PTO extends protection to multicellular organism that is non-naturally occurring).

[74] I discuss the incentives of individual examiners in Part IV.

[75] Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1364 (1992) ("Staff members acting upon matters to which the guidance documents pertain will routinely and indeed automatically apply those documents, rather than considering their policy afresh before deciding whether to apply them.").

time to reflect upon and question official PTO policy;[76] and failure to follow the Agency's official views on substantive law can have negative career repercussions for examiners and even result in termination.[77]

C. *PTO's Lawmaking Power*

While the PTO's views of substantive law are likely to be followed by patent examiners, the Federal Circuit affords no deference to the Agency's

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[76] There are currently over 735,000 patent applications awaiting initial review. PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 38, at 114 tbl.3. It has been estimated that examiners spend roughly eighteen hours on an application, during which time they must read and review the patent application and any amendments, search for and read pertinent prior art, explain in writing why the invention does not meet the patentability requirements, and possibly be interviewed by the prosecuting attorney. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1499–1500 (2001).

[77] The PTO monitors its examiners through a variety of quality assurance mechanisms that are likely to detect examiners who fail to follow PTO directives. These can be divided into three categories. The first set of quality assurance mechanisms are conducted within each technology center and include the collection and analysis of statistics on various work flow product, the assignment of senior examiners to review all work of junior examiners, and the second-pair-of-eyes review. *See* Mark Lemley & Bhaven N. Sampat, *Examiner Characteristics and the Patent Office Outcomes* 7 (Stanford Law & Econ. Olin, Working Paper No. 369, 2009), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1329091 (noting that junior examiner work is subject to review by senior examiners). The second-pair-of-eyes review includes a senior examiner and an examination panel performing an additional review on an application that has been allowed. *Patent Quality Improvement: Expansion of the Second-Pair-of-Eyes Review*, U.S. PATENT & TRADEMARK OFFICE, http://www.uspto.gov/web/offices/com/strat21/action/q3p17a.htm. This program was initially implemented for business method patents only but was later expanded for certain advanced technical fields, such as semiconductors, telecommunication, and biotechnology. *Id.* The Office of Patent Quality Assurance (OPQA) performs the second set of quality assurance mechanisms, including review of a random sampling of allowed patent applications. Historically the OPQA reviews as few as 4% of allowed applications. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF COMMERCE, AUDIT REPORT NO. PTD-9977-7-0001, PATENT QUALITY CONTROLS ARE INADEQUATE 3, graph 1 (1997), *available at* http://www.oig.doc.gov/oig/reports/1997/USPTO-PTD-9977-7-09-1997.pdf. The third set of quality assurance is review of rejected patent applications by the BPAI. In 2009, the BPAI reversed close to 25% of examiner's denials. *See Receipts and Dispositions by Technology Centers for Ex Parte Appeals*, BOARD OF PATENT APPEALS & INTERFERENCES, http://www.uspto.gov/web/offices/dcom/bpai/docs/receipts/fy2009.pdf (listing statistics). The PTO has tied error rates in examination to performance evaluations and an unacceptable error rate can lead to an examiner's termination. USPTO "Quality" Initiatives Mean Slower Production or Unfair Enforcement, PAT. OFF. PROF. ASS'N NEWS, Sept.-Oct. 2003, at 1, 2.

stance on substantive patent law issues. Thus, at first glance, the PTO's power to declare law is limited. While this Article discusses why the Federal Circuit is likely to entrench the PTO's views on substantive law in Part V, the following subpart argues that because so few granted patents are actually litigated, the Federal Circuit is unlikely to see enough cases to fully control the development of substantive patent law. Thus, the PTO's views on substantive patent law, which are not reviewed by the appellate court, are de facto law.

The Federal Circuit itself has remarked that it sees "at most no more than 0.015% of the patents in force."[78] Of course, the appellate court does not need to review every patent to control the development of law; it needs to review only *one* patent in a *class* of patents that are treated similarly under the PTO's official stance on a substantive law issue. However, especially with emerging technology, any single case may not present the full range of the PTO's views. Parties to an individual case make arguments that best serve their claims or broader objectives. These litigant-driven decisions necessarily constrain the set of legal standards that the court can address. Thus, the Federal Circuit may need to review a significant number of patents in a particular class to review the full range of the PTO views on emergent technology (i.e., PTO's views on patentable subject matter, novelty, nonobviousness, etc.).

The very small set of issued patents that are litigated make it unlikely that the set of issues that come before the Federal Circuit are a representative sample of the PTO's views on substantive patent law. There is growing empirical evidence that litigated patents differ substantially from patents that are never litigated.[79] For example, litigated patents tend to come disproportionately from certain industries. Patents on medical devices and mechanics are much more likely to be litigated than semiconductor or chemistry patents.[80] Further, the PTO maintains that the patent applications before it differ in significant ways from the set of patents that the Federal Circuit reviews. In particular, the Agency contends that it rejects a significant

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[78] Morton Int'l, Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 1472 (Fed. Cir. 1993) (Mayer, J., concurring).

[79] John R. Allison et al., *Valuable Patents*, 92 GEO. L.J. 435, 437–38 (2004); *see also* John R. Allison & Thomas W. Sager, *Valuable Patents Redux: On the Enduring Merit of Using Patent Characteristics to Identify Valuable Patents*, 85 TEX. L. REV. 1769 (2007); John R. Allison, Mark A. Lemley & Joshua Walker, *Patent Quality and Settlement Among Repeat Patent Litigants* (Stanford Law & Econ. Olin, Working Paper No. 398, 2010), *available at* http://ssrn.com/abstract=1677785 (noting that 93.7% of the most-litigated patents—patents litigated at least eight times—are software patents).

[80] Allison, Lemley & Walker, *supra* note 79.

number of patent applications on the written description requirement alone whereas the Federal Circuit rarely reviews such cases.[81]

Notably, even when the Federal Circuit does review the PTO's official position on substantive patent law, it is important to realize that up to this review, the PTO's viewpoints were likely governing patent applications for a significant period of time.[82] While the PTO can develop and implement its stance on substantive law in a relatively short timeframe, it will generally take years, and sometimes even decades, before the Federal Circuit is given the opportunity to review the PTO's views on substantive law through a granted patent.

III. THE PTO'S ASYMMETRIC INCENTIVES

Part II demonstrated that the PTO has a much larger practical effect on the development of substantive law than is generally recognized. Recognizing the import of the PTO in setting substantive standards gives rise to a number of significant implications. First, as a descriptive matter, the account of patent law that focuses exclusively on the Federal Circuit is misleading. The current literature generally ignores one of the richest sources of substantive patent law. Second, because the PTO's views on substantive law have a significant effect on patent policy, the process by which the PTO crafts these rules should come under more scrutiny. Currently, much of PTO policymaking occurs in a black box, with little transparency or oversight. Third, the current policy discussions about patent reform and industry-specific patent law have largely overlooked a crucial player in current policy-setting. For example, Dan Burk and Mark Lemley have persuasively argued that substantive patent law should be tailored to better reflect the industry-specific nature of innovation.[83] They delineate "policy levers" within substantive patent law that can take into account economic considerations of how innovation works in various technological fields.[84] Yet, they fail to give any serious consideration to granting the PTO substantive rulemaking authority, noting that the Agency does not have personnel trained with any

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[81] Oral Arguments at 23:20, Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (No. 2008-1248-2), *available at* http://oralarguments.cafc.uscourts.gov/oral-argument-recordings/2008-1248-2/all (PTO argues that it rejects a large number of patent applications on the doctrine of written description alone even though the Federal Circuit rarely sees such cases).

[82] For example, the 2001 Utility Examination Guidelines were highly controversial, but the Federal Circuit did not rule on their legitimacy until September 2005. *In re* Fisher, 421 F.3d 1365, 1372 (Fed. Cir. 2005).

[83] *See* BURK & LEMLEY, *supra* note 35, at 109.

[84] *Id.*

innovative policy expertise.[85] This view of the PTO, however, largely ignores the reality that the Agency *already* does a fair amount of rulemaking in the form of substantive guidance to examiners and patent applicants. It is thus time to think more carefully about using the PTO to handle certain issues,[86] or at least learn from the Agency's experiences.

Finally, and perhaps most importantly, the fact that the PTO is playing an important role in shaping the contours of substantive law also necessitates an exploration of how the Agency's institutional biases can affect the development of substantive patent law. While the PTO's stance on substantive law issues is undoubtedly guided by its mission of fostering innovation and competition by providing high quality examination of patent applications,[87] like many agencies (and individuals), the PTO is also self-interested in ways that may conflict with its public interest mission. The remainder of this Part identifies two institutional features of the PTO, each of which, when coupled with the PTO's natural self-interestedness, bias the PTO's views on substantive law in a patent-protective direction. This Part refers to these institutional features—unidirectional review of PTO decisions by the Federal Circuit and the PTO's fee structure—as asymmetric because they generally push the PTO's views on substantive patent law in an expansive direction.

A. *Asymmetric Review*

This subpart explores how the asymmetric review of PTO determinations is likely to distort the Agency's views of substantive patent law. In a recently posted working paper, Jonathan Masur has explored a similar line of thought and largely reaches the same conclusion regarding the effect of asymmetric review on PTO decision making.[88] While the current analysis concerns the PTO, to some extent it also involves other administrative agencies.[89] In the patent system, judicial review of PTO decisions is unidirectional—patent denials are subject to immediate review by the Federal Circuit whereas patent grants are not. In at least a subset of other administrative agency decisions,

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[85] *Id.* at 168 (describing the PTO as having "virtually no policy staff").

[86] *See, e.g.*, Michael Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. (forthcoming 2011), *available at* http://ssrn.com/abstract=1718695 (arguing that the PTO should be given substantive rulemaking authority).

[87] PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 38, at 8.

[88] *See* Masur, *supra* note 17.

[89] There are at least two other agencies that have formal asymmetries: the Social Security Administration for Supplemental Security Income or Social Security Disability Insurance, *see* 42 U.S.C. § 405 (2006), and decisions by the Board of Immigration Appeals for removal and asylum, *see* 8 U.S.C. § 1158 (2006).

factors such as unequal stakes in the litigation or unequal finances to fund litigation may also cause parties on one side of an agency decision to appeal more frequently.[90] Asymmetric rates of appeal can create substantial asymmetry in the judicial review of determinations, although the magnitude of the asymmetry will be less than the PTO's.

The PTO, like many other decision makers, is concerned with both the possibility of appeal and reversal of its determinations.[91] Appeals of PTO decisions are costly to the Agency, as the PTO must defend its actions in court. The PTO operates on a fixed budget and thus resources that it devotes to litigation are resources that it necessarily cannot devote to more pressing needs—such as updating the Agency's outdated technology system.[92]

Appeals of PTO decisions are also costly to the Agency because it risks reversal. If the PTO is repeatedly overturned by the Federal Circuit, other patentees may challenge the Agency's rulings with greater frequency, thus adding to the PTO's litigation costs.[93] Reversal by the Federal Circuit may

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[90] For example, if regulated entities are more likely to sue the United States Department of Agriculture (USDA) than food safety groups, then USDA regulations are more likely to be challenged as too stringent than as too lax. The asymmetric appeal rates can create an informal asymmetry in the judicial review of USDA decision making.

[91] Scholars have long posited that for the most part, judges are concerned with their records and detest having their determinations be overturned. *See* Delaware v. Van Arsdall, 475 U.S. 673, 686 (1986) (White, J., concurring) ("No judge welcomes or can ignore being told that he committed a constitutional violation, even if the conviction is saved by a harmless-error finding."); RICHARD A. POSNER, THE PROBLEMS OF JURISPRUDENCE 224 (1990) ("[M]ost judges are highly sensitive to being reversed . . . ."); Evan H. Caminker, *Precedent and Prediction: The Forward-Looking Aspects of Inferior Court Decisionmaking*, 73 TEX. L. REV. 1, 77–78 (1994) (discussing reasons why district court judges dislike being reversed on appeal).

[92] Diane Bartz, *Ex-IBM Exec Tries to Reboot U.S. Patent Office*, REUTERS (Jan. 26, 2010), http://www.reuters.com/article/2010/01/26/us-usa-budget-patents-idUSTRE60P66220100126 ("An antiquated computer system which crashes and idles thousands of workers is 'frankly embarrassing' says U.S. Patent and Trademark Office Director David Kappos, a former International Business Machines executive who estimates it would take several hundred million dollars to upgrade.").

[93] Consider the experience of the Social Security Administration (SSA). During the mid-1980s, the reversal rate of SSA decisions in federal district court soared to near 50%. The constituencies of the SSA took notice, and the number of appeals filed in federal court tripled from the early 1980s to the mid-1980s. *See* A. Leo Levin & Michael E. Kunz, *Thinking About Judgeships*, 44 AM. U. L. REV. 1627, 1650 (1995) (stating that litigants were encouraged by the high reversal rate to pursue appeals of Social Security Administration decisions). By the early 1990s the reversal rate of the SSA in federal court decreased to near 20% and so too had the number of appeals filed in federal court. *See* Paul R. Verkuil, *Reflections Upon the Federal Administrative Judiciary*, 39 UCLA L. REV. 1341, 1355 n.57, 1356 n.61 (1992).

also cause reputational harm.[94] Repeat players, such as the PTO, believe their reputation is largely their stock in trade.[95] However, routine reversal by the

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[94] The PTO may also be concerned that its reputation before Congress would suffer if its status as a fair arbitrator is called into question. While the PTO is a fee-funded agency, Congress must still approve the PTO's budget every year. The PTO lacks substantial fee-setting capabilities and is therefore beholden to Congress for fee increases. Further, the PTO has expressed interest in obtaining substantive rulemaking—a change that, at this point, could only occur through congressional action. Letter from Gary Locke, Sec'y of Commerce, to Patrick J. Leahy & Jefferson B. Sessions, U.S. Senators (Oct. 5, 2009), *available at* http://www.ogc.doc.gov/ogc/legreg/letters/111/S515Oct0509.pdf ("Current law limits the USPTO Director's ability to implement needed reforms through the promulgation of administrative regulations. . . . Substantive rulemaking authority would remove doubt raised regarding the USPTO Director's authority to adopt rules in light of *Tafas v. Dudas*, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008); aff'd in part, rev'd in part, *Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. March 20, 2009); vacated, petition for rehearing en banc granted (Fed. Cir. July 6, 2009). Furthermore, substantive rulemaking authority would give the USPTO Director the ability to provide flexibility in the administration of patent rules and procedures.").

[95] Scholars have long recognized that repeat players are more concerned with their credibility before a court than so-called one-shot players. *See, e.g.*, Marc Galanter, *Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change*, 9 LAW & SOC'Y REV. 95, 98–99 (1974); Hon. Fred I. Parker, *Appellate Advocacy and Practice in the Second Circuit*, 64 BROOK. L. REV. 457, 462 (1998). Concerns with maintaining institutional credibility before the Federal Circuit can be seen in the decision making process of the PTO. Specifically, this concern has manifested itself with respect to the PTO's decisions regarding whether to seek certiorari review of Federal Circuit decisions. Routinely challenging the validity of Federal Circuit opinions is risky for the PTO. The Federal Circuit, whose jurisdiction rarely overlaps with the jurisdiction of other appellate courts, is somewhat isolated from inter-circuit debate regarding issues. Several scholars posited that this isolation has caused the Federal Circuit to be less comfortable with criticism than other circuits. *See* Dreyfuss, *Pathological Patenting*, *supra* note 33, at 1570 (discussing how Federal Circuit judges have developed "thin skins"); Craig Allen Nard, *Toward a Cautious Approach to Obeisance: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, 39 HOUS. L. REV. 667, 673–74 (2002) (finding that the Federal Circuit is less likely to cite academic literature than other circuits).

Since the inception of the Federal Circuit in 1982, the PTO has never sought certiorari review of a Federal Circuit decision on a patent law issue. The sole case in which the Agency did seek Supreme Court review of a Federal Circuit decision, *Dickinson v. Zurko*, 527 U.S. 150 (1999), involved the applicability of the Administrative Procedure Act. This lack of review has occurred despite growing criticism of the state of patent law jurisprudence since the late 1990s, *see, e.g.*, NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 81–83 (Stephen A. Merrill et al. eds., 2004); NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 11–15 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006) (suggesting that the standard for nonobviousness is too low, that the utility requirement is under-enforced, that doctrinal

Federal Circuit may undermine the Agency's credibility before the court, mitigating some of the PTO's repeat player advantage.[96]

Assuming that the PTO is incentivized to minimize Federal Circuit scrutiny and reversal of its decision making, it is reasonable to ask how this incentive will affect its decision making. Most administrative agencies (and judges) always bear some risk of reversal because their decisions are potentially appealable by the aggrieved party—i.e., constituencies that are on either side of an issue. In such cases, the decision makers' natural interest in avoiding reversal, coupled with the possibility of appeal by either of the two sets of constituents, will be neither frustrated nor furthered by systematically favoring one side over the other. Such two-sided review thus frees an agency to attempt to arrive at an answer that is dominated by considerations of the public interest as well as the legal precedent.

In contrast, the unidirectional review of PTO decisions means the Agency can avoid any risk of reversal and any costs associated with immediate review of its decision making by granting a patent. In a system where there is no immediate appeal of patent grants[97] but there is the possibility for immediate judicial review of patent denials,[98] the PTO could

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changes have inhibited follow-on invention, and that subjective elements in patent doctrine increase costs and discourage inventors from conducting library research), and rumors that the PTO was unhappy with several Federal Circuit decisions, *see, e.g.*, Dreyfuss, *Pathological Patenting*, *supra* note 33, at 1570 (discussing the fact that although the PTO was rumored to be unhappy with a Federal Circuit decision, the PTO did not seek further review). This dearth of filings of certiorari petitions by the PTO stands in contrast to the two decades prior to the creation of the Federal Circuit. In this time period the PTO sought certiorari in more than a half-dozen cases. Nard & Duffy, *supra* note 7, at 1641 n.79. This decrease in certiorari filings is consistent with an agency that is concerned with maintaining its institutional credibility before a court.

[96] Courts tend to be more critical of decision makers with poor reputations than decision makers with outstanding reputations. *See* Robert E. Hawkins & David M. Shoemaker, *Reputational Review II: Administrative Agencies, Print Media & Content Analysis*, 12 CAN. J. ADMIN. L. & PRAC. 1 (1998) (arguing that judicial review of agency decisions has morphed from focusing on the legality of the decision to the reputation of the decision maker); Paul R. Verkuil, *An Outcomes Analysis of Scope of Review Standards*, 44 WM. & MARY L. REV. 679, 707–08 (2002) (arguing that the reversal rate of SSA is significantly higher than the substantial evidence scope of review would predict and this high rate of reversal stems, in part, from "entrenched judicial skepticism" about the "fairness and accuracy" of the SSA's decision making process).

[97] A patent is issued on an invention that is new, 35 U.S.C. § 101 (2006), novel, *id.* § 102, non-obvious, *id.* § 103, constitutes patentable subject matter, *id.* § 101, is adequately described, *id.* § 112, and enabled, *id.* § 112.

[98] *See* 35 U.S.C. § 134 (2006) (outlining when a party may seek a Board appeal); *id.* § 141 (permitting appeals of Board decisions to the Federal Circuit). An applicant can also undertake civil action in the District Court for the District of Columbia. Any appeals

completely avoid litigation and any possibility of reversal by interpreting and developing substantive law so that every invention meets the patentability standards. There are, of course, many reasons why the PTO would not take such a drastic measure, including the Agency's mission for promoting "industrial and technological progress in the United States and strengthen[ing] the national economy."[99]

The PTO's desire to avoid scrutiny of its decision making and risk of reversal can, nonetheless, have profound effects on the development of substantive patent law. When the Agency is faced with a close legal issue, high level officials will develop rules or patent policy that allow for the patentability of these inventions. In other words, the PTO interprets and develops substantive patent law so that it grants patents when it believes the patent application would either just meet or just not meet the patentability standards. Thus, PTO examiners will be instructed to utilize patentability standards through either guidance documents or BPAI decisions that are biased in the patent-protective direction.[100] In this way the Agency is able to ensure that the majority of patents it denies are likely to be upheld by the Federal Circuit.[101]

Finally, it should be noted that even though the PTO can avoid direct appeal by granting patents, its decisions can still be challenged in a subsequent patent infringement suit or declaratory judgment action. As a result, it is possible that the threat of this subsequent judicial review may discipline the PTO and mitigate the expansionary bias described above.

Yet, from the PTO's perspective, patent grants and patent denials are not fungible. There are a number of reasons why the PTO would prefer that a granted patent be invalidated rather than a patent denial be reversed. First,

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from the District Court for the District of Columbia involving patent denials can then be appealed to the Federal Circuit. 35 U.S.C. § 145 (2006) (permitting appeals of Board decisions to the U.S. District Court for the District of Columbia). In 2008, 25% of patent applicants sought review by the U.S. District Court for the District of Columbia, whereas 75% appealed directly to the Federal Circuit. In 2007, 30% of patent applicants chose civil action before the U.S. District Court for the District of Columbia, and 70% appealed directly to the Federal Circuit. Appealing the Board decision is not the only option for a patent applicant. An applicant whose application has received a "final rejection" by the examiner may choose to start the prosecution process over by filing a continuation application or a request for continued examination. 35 U.S.C. § 120 (2006).

[99] *Patent and Trademark Mission*, U.S. PATENT AND TRADEMARK OFFICE, http://www.uspto.gov/web/menu/mission.html. This mission is likely to prevent the Agency from ever advocating that its examiners grant all patents.

[100] Biased in the sense that if the PTO only took into account its mission statement it would arrive at a non-biased standard.

[101] This analysis assumes that the Federal Circuit will also only take into account the public interest and hence believes the non-biased standard is the correct result.

the PTO is almost never a party when a granted patent is litigated, and hence the Agency is not responsible for the litigation costs associated with defending a patent grant. Second, high-level officials of the PTO are more likely to be concerned about the PTO's present reputation than its future reputation. The average time delay between the issuance of a patent and the final validity decision, which is 8.6 years,[102] is greater than the average tenure of PTO directors (as well as the vast majority of patent examiners).[103]

Finally, there are at least three reasons why the reversal of a patent denial is more likely to reflect poor decision making by the PTO and hence possible reputational harm to the Agency, than the invalidation of a granted patent. First, a court may decide that a granted patent is invalid on an issue that was never before the PTO. In contrast, when a patent applicant appeals a patent denial, she is precluded from presenting new issues absent some compelling reason that the issue was not presented before the PTO.[104] Second, even when a court decides the validity of a granted patent on an issue the PTO has considered, the court is likely to have the luxury of considering more evidence (i.e., new prior art) than the PTO.[105] Third, the law may have changed from when the PTO issued the patent to when the court invalidated the patent.[106] Thus, it seems unlikely that the threat of subsequent judicial review of patent grants will have any mitigating effect on the PTO's expansionary bias described above.

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[102] Allison & Lemley, *supra* note 12, at 236 tbl.12. For a quarter of all patents reaching final judgment in a district court action, more than eleven years elapse. U.S. DEP'T OF COMMERCE, PATENT REFORM: UNLEASHING INNOVATION, PROMOTING ECONOMIC GROWTH & PRODUCING HIGH-PAYING JOBS 8 (2010), *available at* http://www.commerce.gov/s/groups/public/@doc/@os/@opa/documents/content/prod01_009147.pdf.

[103] As the Director of the PTO is nominated by the President and approved by the Senate, 35 U.S.C. § 3 (2006), the leadership of the PTO changes as the Administration in the White House changes.

[104] *See* DeSeversky v. Brenner, 424 F.2d 857, 858–59, (D.C. Cir. 1970) (affirming dismissal of patent applicant's § 145 action seeking to set aside an obviousness rejection where the applicant failed to show that the PTO had erred in originally rejecting the claim and the new testimony it presented to show nonobviousness focused on the presence of a structural feature that the applicant had not presented to the PTO).

[105] Allison & Lemley, *supra* note 12, at 208 tbl.1 (42% obviousness and 27% novelty prior art).

[106] Consider, for example, means-plus-function claims of computer software patents. Harris Corp. v. Ericsson, Inc., 417 F.3d 1241, 1253 (Fed. Cir. 2005); WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1347 (Fed. Cir. 1999).

B. *Asymmetric Funding*

While the unidirectional review of PTO determinations gives rise to a protective patent bias in the PTO's views on substantive patent law, in general, so too do the PTO's financial incentives. The PTO is a self-funded agency that obtains its entire budget through user fees.[107] Several scholars have suggested that the fact that the Agency is user fee funded may lead it to make decisions that favor its constituency at the expense of the public.[108] At least one scholar, Arti Rai, has noted that the specific fee structure of the PTO creates a financial incentive for the PTO to grant patents, although her limited treatment of the issue did not fully examine the distortions caused by the specific fee structure of the Agency or the interplay between these distortions and the Agency's nontrivial role in substantive law development.[109] This Part moves beyond these more preliminary discussions and argues that fee structure of the PTO does not merely result in examiners randomly issuing invalid patents. More profoundly, because the PTO is actually designing and influencing patent policies, the Agency's financial incentives to grant patents can have a strong and direct effect on the content of substantive patent law.

The PTO garners over 80% of its patent operating budget[110] through three types of fees: a filing, search, and examination fee (collectively referred

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[107] The PTO budget is set to the amount of projected revenue it will collect through user fees. The PTO has been funded by user fees since 1990. Omnibus Reconciliation Act of 1990, Pub. L. No. 101-508, § 10101, 104 Stat. 1388, 1388–91 (1990).

[108] *See* Benjamin & Rai, *supra* note 16, at 314 ("[PTO] is favorably disposed to patent holders . . . [in part because] the agency as a whole is funded by applicant fees."); Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 579 n.178 (2009) ("A pro-patent bias also arises because the PTO is wholly funded by patent-applicant fees."); Long, *supra* note 19, at 1994 ("[T]he PTO's budgetary structure creates a bias in favor of granting patents and encouraging inventors to apply for patents. It also creates the incentive for the PTO to favor patentees (who pay fees to the PTO) over nonpatentees (who do not)."); Meurer, *supra* note 36, at 699 ("The PTO has endorsed a 'customer service' orientation that stresses the importance of meeting the needs of patent applicants. This orientation may be motivated in part by the dependence of the [A]gency on fees to fund its operation.").

[109] Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2062 (2009) ("[T]he current fee structure also sets up an obvious financial incentive for the PTO to grant patents.").

[110] The patent operating budget accounts for close to 90% of the PTO's total operating budget. *See* PERFORMANCE AND ACCOUNTABILITY REPORT, supra note 38, at 46–49 (noting that the PTO's total earned revenue in the fiscal year of 2009 was $1.927 billion, of which approximately 90% was earned through patent revenues while the remaining 10% was earned through trademark revenues).

to as examination fees), which is paid when a patent application is filed; an issuance fee, which is paid when a patent issues; and maintenance fees or renewal fees, which are paid periodically on granted patents so that they remain enforceable.[111] While examination fees account for approximately 30% of the PTO budget, these fees do not cover the actual cost incurred by the PTO to perform these services.[112] Consider, for example, that in the fiscal year 2009 the PTO estimated that the average cost of examining a patent application was approximately $3,500.[113] The examination fees are only $1,090 for large for-profit corporations and half that amount for individuals, small firms, non-profit corporations, or other enterprises that qualify for "small entity" status.[114] Therefore, the paid examination fees cover less than one-third of the actual examination costs for large corporations and less than one-sixth of actual costs for small entities.

The PTO is dependent on issuance fees and maintenance fees, which account for almost 50% of the PTO's patent operating budget, to subsidize the cost of the Agency's examination process. In its 2009 fiscal year, the issuance fee was set at $1,510,[115] and the maintenance fees, which are due at three-and-a-half, seven-and-a-half, and eleven-and-a-half years, were $980, $2,480, and $4,110, respectively.[116] Again, these amounts are halved for small entities. Unlike the examination process, the costs to the Agency of issuing and maintaining a patent are virtually negligible. Fees paid for these services are almost pure profit for the Agency. Furthermore, once a patent is granted, the PTO's involvement with that patent usually ends.[117] In other

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[111] *Id.* at 49 (stating that approximately 80% of total patent income comes from maintenance fees, initial application for filing, search, and examination and issue fees).

[112] *Id.* (stating that 31.3% of total patent income comes from filing, search, and examination fees).

[113] *Id.* at 37 (stating that in 2009, the average patent cost $3,523 to examine).

[114] 37 C.F.R. § 1.16(a)(1) (2010) (basic filing fee is $330 and $165 for small entity); *id.* § 1.16(k) (utility search fee is normally $540 and $270 for small entity); *id.* § 1.16(o) (utility examination fee is normally $220 and $110 for small entity). An entity is defined by the PTO as individuals, nonprofit organizations, or business entities that qualify as small businesses under the Small Business Act. *Id.* § 1.27(a)(1)–(3).

[115] 37 C.F.R. § 1.18(a) (2010).

[116] *Id.* § 1.20(e-g).

[117] The sole exceptions are ex parte and inter partes reexamination. 35 U.S.C. §§ 301, 303 (2006). These two procedures provide a limited administrative procedure for reviewing granted patents. Both of these procedures suffer from having narrow substantive grounds for review and strict estoppel provisions. Ex parte reexamination bars the participation of a third party once the PTO has determined whether a reexamination should commence. 37 C.F.R. § 1.550(g) ("The active participation of the *ex parte* reexamination requester ends with the reply pursuant to § 1.535, and no further submissions on behalf of the reexamination requester will be acknowledged or

words, the Agency does not usually have to allocate any additional resources to a patent once it has been granted. The result is that the majority of the PTO's budget is gained through fees that the Agency only collects if a patent is granted.[118] This fact, along with the cross-subsidization of the examination process by issuance and maintenance fees, sets up an obvious financial incentive for the PTO to grant, rather than deny, patents.

Yet, denying a patent will likely cost the PTO more than just the missed opportunity of obtaining post-allowance fees. When a patent application is denied, the applicant can choose one of three options. First, the patent applicant can abandon the application, in which case the PTO loses the differential between the cost of examining the patent and the examination fees. Second, the patent applicant can choose to appeal the denial to the BPAI and seek review of a BPAI denial in federal court.[119] If the patent applicant seeks federal review, the PTO must utilize its own legal office to defend its actions in court.[120] Third, an applicant can elect to "restart" the patent examination process by filing a request for continued examination (RCE) or by filing a continuation application.[121] By filing such a request, a

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considered."). Inter partes reexamination allows for third-party participation but in a limited manner—the third party has the right to file written comments addressing "issues raised by the Office action or the patent owner's response." *Id.* § 1.947. These problems have had a dramatic effect on the number of reexaminations requests. For example, in 2009, only 258 inter partes reexaminations were filed while over 165,000 utility patents issued. PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 38, at 116 tbl.6, 124 tbl.13.

[118] Of course, there may be good innovation policy reasons to have maintenance fees that are substantial and escalate over time. *See, e.g.*, Francesca Cornelli & Mark Schankerman, *Patent Renewals and R&D Incentives*, 30 RAND J. OF ECON. 197 (1999) (demonstrating that under certain circumstances the socially optimal patent system involves increasing renewal fees); Suzanne Scotchmer, *On the Optimality of the Patent Renewal System*, 30 RAND J. OF ECON. 181 (1999) (same).

[119] *See* 35 U.S.C. § 134 (2006) (outlining when a party may seek a Board appeal); *id.* § 141 (permitting appeals of Board decisions to the Federal Circuit); *id.* § 145 (permitting appeals of Board decisions to the U.S. District Court for the District of Columbia).

[120] A patent applicant must pay a notice of appeal fee of $540, 37 C.F.R. § 41.20(b)(1) (2010), a fee to file a brief in support of an appeal of $540, *id.* § 41.20(b)(2), and a fee to request for oral hearing of $1080, *id.* § 41.20(b)(3). It is not clear how much the PTO spends on a BPAI hearing. However, even if these fees cover the PTO's costs, it seems unlikely that a surplus would offset the revenue that the PTO loses by defending actions before federal courts.

[121] A patent applicant who files a continuation application files an entirely new application, although the new application can share the same filing date as the "parent." In contrast, a patent applicant who files an RCE is requesting continued prosecution of the existing application. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent*

"finally rejected" patent application receives continued examination by the PTO.[122] The fees for examining an RCE are set below the examining fees for a new application and the fees for examining a continuation application are the same as a new application.[123] While the costs to the PTO of continued examination are probably less than the original examination, the savings are unlikely to reach the amount required to align fees with costs. There is a high likelihood that at least some of the potential cost savings of continued examination (i.e., the examiner does not have to reread the patent application or reread the pertinent prior art) are unlikely to be realized because of high examiner turnover.[124] Thus, the mismatch in examination fees and examination costs for a patent application are likely to increase with each iteration through the examination system. These additional costs of denying a patent reinforce the incentive to grant, rather than deny, patents that is inherent in the fee structure of the PTO.

It would be difficult to empirically test the extent to which the financial incentive to grant patents influences the PTO's views of substantive patent law. Nonetheless, there are reasons to believe that this incentive impacts the decisional process of the Agency. Budgets are undeniably important to agencies. Scholars have posited that agency leaders seek to maximize their budgets or profit because these entities are positively correlated with other goods that a bureaucrat values, such as compensation, prestige and prospects for advancement, and the ability of the agency to carry out its mission.[125] While the universal nature of the budget- or profit- maximizing bureaucrat

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Continuations, 84 B.U. L. REV. 63, 68 n.14 (2004). The use of these practices is fairly widespread. It has been estimated that approximately a quarter of all patents granted result from the use of continuation. *See id.* at 69. Also, continuations have a longer history than RCE, the latter of which have only existed since 1999. *See* American Inventors Protection Act of 1999, Pub. L. No. 106-113, sec. 4403(2), § 132(b), 113 Stat. 1501A-552, 1501A-560 (codified as amended at 35 U.S.C. § 132(b) (2006)) (establishing RCEs).

[122] *See* Lemley & Moore, *supra* note 121, at 64 ("One of the oddest things about the United States patent system is that it is impossible for the U.S. Patent and Trademark Office ('PTO') to ever finally reject a patent application.").

[123] In its 2009 fiscal year, the request for continued examination fee was $810 for a large entity and $405 for a small entity. 37 C.F.R. § 1.17(e) (2010).

[124] U.S. GOV'T ACCOUNTABILITY OFFICE, U.S. PATENT AND TRADEMARK OFFICE: HIRING EFFORTS ARE NOT SUFFICIENT TO REDUCE THE PATENT APPLICATION BACKLOG 13 (2007), *available at* http://www.gao.gov/new.items/d071102.pdf (discussing high patent examiner attrition rates).

[125] *See generally* THE BUDGET-MAXIMIZING BUREAUCRAT: APPRAISAL AND EVIDENCE (André Blais & Stéphane Dion eds., 1991); WILLIAM A. NISKANEN, JR., *Bureaucracy and Representative Government*, *in* BUREAUCRACY AND PUBLIC ECONOMICS 3, 38–41 (1994).

has been questioned,[126] it seems that even a benevolent agency—an agency that merely strives to perform its mission and not maximize its budget or profit—will seek increased funding if its current budget falls short of the amount required for the agency to perform its expected duties. There is widespread agreement that the present budget of the PTO is insufficient for the Agency to carry out its expected responsibilities.[127] The Agency has a backlog of 735,000 patent applications awaiting initial review and a growing wait time before the Agency acts on a filed patent application. Therefore, even if the PTO does not have an imperialistic motive of profit maximization, it seems likely that it will seek to increase its budget so that it can meet its expected output or responsibilities.

Given that the PTO is looking to augment its budget,[128] how then will this incentive affect the PTO's views on substantive law? The PTO will

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[126] *See* JAMES Q. WILSON, BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT 182 (1989) ("The view that all bureaus want larger budgets ignores the fact that there is often a tradeoff between bigger budgets on the one hand and the complexity of tasks, the number of rivals, and the multiplicity of constraints on the other."); Daryl J. Levinson, *Empire-Building Government in Constitutional Law*, 118 HARV. L. REV. 915, 917-20 (2005) (arguing that empire-building of agencies is overstated because bureaucrats do not have the same motives as corporate leaders).

[127] FED. TRADE COMM'N, *supra* note 8, at 10 ("Hearings participants unanimously held the view that the PTO does not receive sufficient funding for its responsibilities.").

[128] The PTO lacks fee-setting authority and thus needs to lobby Congress for any budget increase. Currently, any significant change in the filing fees, issuance fees, and maintenance fees requires congressional action. *See* 35 U.S.C. § 41(d) (2006) (limiting the PTO's discretion in setting fees to minor issues such as "processing, services, or materials"). The PTO has enjoyed limited success in convincing Congress to increase its budget. For example, the PTO was able to end the controversial practice known as "fee-diversion." Long, *supra* note 19, at 1986–87. However, support from the users of the patent system has been more mixed with respect to the PTO's proposals to increase its fees. Campaigns in 1990 and 1991 to end small entity status and a 2002 campaign to increase fee levels and restructure fees were largely unsuccessful because patent applicants did not support these increases. *See* Traci Watson, *Patent Office Drops Plan to Raise Fees*, 356 NATURE 645, 645 (1992) (noting that after "failing twice to convince Congress that small-scale inventors do not deserve a price break, the US Patent and Trademark Office (PTO) has dropped its opposition to such a discount" and that "small inventors convinced Congress that a higher maintenance fees [sic] would weaken the US economy"). The PTO is currently seeking the ability to set its own fees, in part to better align fees with costs, U.S. PATENT & TRADEMARK OFFICE, FISCAL YEAR 2011 PRESIDENT'S BUDGET 2, 8 (2010), *available at* http://www.uspto.gov/about/stratplan/budget/fy11pbr.pdf, but patent owners do not appear to support this initiative, *see, e.g.*, U.S. Patent Reform Primer, *No. 4 Senate Bill Shifts Authority to Set Patent and Trademark Fees*, INTELLECTUAL PROPERTY OWNERS ASS'N (Jan. 9, 2011, 9:35 AM), http://www.ipo.org/AM/Template.cfm?Section=IPO_Daily_News_&CONTENTID=243

generally interpret and develop substantive law in an expansive manner in an effort to grant more patents. The PTO could maximize its budget by granting every patent. However, such a drastic practice is unlikely, as the PTO is motivated by other concerns than just the size of its budget. Similar to asymmetric review, asymmetric funding of the Agency is most likely to manifest in the marginal or close cases. Thus, the PTO will adopt expansionary positions with respect to patent law in order that close legal issues are decided in favor of the patentee.

Although the PTO's basic fee structure preferences patent grants over denials, not all patent grants generate equal revenue for the PTO. If a higher percentage of patents in technology *X* are maintained than in technology *Y*, then, on average, an issued patent in technology *X* will generate more revenue than issued patents in technology *Y*. Thus, if the PTO seeks to maximize its potential income by granting more patents, the PTO has an incentive to grant more patents in technology fields with the highest chance of patent renewal. Kimberly Moore—now Judge Moore on the Federal Circuit—found that renewal rates vary greatly across technology fields. Specifically, she found that patents on semiconductors and electrical devices, communications, and computer technology are more likely to be maintained than mechanical patents and that mechanical patents are more likely to be maintained than biotechnology and pharmaceutical patents.[129]

05&TEMPLATE=/CM/HTMLDisplay.cfm#4 ("IPO for many years has opposed shifting fee-setting authority to the USPTO.").

[129] Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521, 1540 (2005). The amount of revenue, on average, the PTO will collect per patent issued also depends on whether the patent owner is a small entity, as small entities pay half the renewal fees of other patent owners. At the time of filing, renewal rates and the percentage of small entity filers in a technology field are generally negatively correlated. For example, biotechnology and pharmaceutical patents are less likely to be renewed once granted but also more likely of being filed by patent applicants claiming small entity status (36% of patent applications are filed by small entity filers). In contrast, patents granted in semiconductors and computer technology fields are more likely to be renewed but are less likely of being filed by a patent applicant claiming small entity status (17% and 16% respectively). Thus, at least based on characteristics of the patent applicants at the time of filing, the PTO stands to collect less revenue for a patent issued in the biotechnology and pharmaceutical field not only because the patent is less likely to be renewed but also because when the patent owner does renew the patent, it is more likely to pay half the fees. E-mail from David Wiley, Acting Dir., Office of Planning and Budget, U.S. Patent & Trademark Office, to author (Sept. 23, 2010, 2:50 PM) (on file with author) (providing data on the percentage of small entity filers by technology field for the fiscal years of 2005–2010). However, the data regarding small entities is only at the time of filing and does not take into account whether the patent has been transferred to a large entity after it was issued. While it is unclear how frequently patents are transferred, litigated patents that were originally issued to individuals have a very high

The likelihood of maintenance is generally consistent with the PTO's most recent granting patterns.[130] Semiconductors and electrical device patents are the most likely to be granted—nearly 80% of patent applications in this technology field issue.[131] Communications and computer technology also have high grant rates of 68% and 65%, respectively.[132] In contrast, only 57% of mechanical patent applications and 45% of biotechnology and pharmaceutical patent applications issue.[133] From a social welfare perspective, this field-specific incentive to grant patents is troubling, as patents on computer technology and software, a technological field with one of the highest renewal rates, are generally believed to be some of the least socially valuable.[134]

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transfer rate. *See* Hon. Kimberly A. Moore, *Populism and Patents*, 82 N.Y.U. L. REV. 69, 96–97 (2007) (finding that 39.7% of litigated patents were transferred and that 42.3% of patents that corporations litigated were acquired after issuance and that almost all of these were originally issued to individuals).

[130] These technology fields are broad and inevitably include some heterogeneity in grant rates across subdivisions. *See* Dennis Crouch, *USPTO Grant Rate by Technology Center*, PATENTLY-O (May 27, 2010, 2:24 AM), http://www.patentlyo.com/patent/2010/05/uspto-grant-rate-by-technology-center.html; U.S. PATENT & TRADEMARK OFFICE: PATENT TECHNOLOGY CENTERS, http://www.uspto.gov/about/contacts/phone_directory/pat_tech/ (last visited Jan. 29, 2011) (technology centers listed by code). *But see* Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 182 (2008) (finding that the PTO grants a lower percentage of patents for computer architecture, software, and information security patents and a higher percentage of patents for biotechnology and pharmaceuticals). The Lemley and Sampat sample included every utility patent application filed in January 2001 and published in April 2006, which consisted of approximately 10,000 patent applications. *Id.* at 187.

[131] Crouch, *supra* note 130.

[132] *Id.* This data set includes 25,000 utility patent applications from the past few years.

[133] *Id.*

[134] Surveys of software firms have consistently reported that patents do not provide strong protection of their inventions and serve as weak incentives to innovate. Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 793–99 (1987) (surveying R&D managers about the efficacy of patents and finding that respondents rated patents as the least effective method of appropriation and preferred other devices to protect returns on investments); Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961, 997–98 (2005) (same). Recent empirical work of James Bessen and Michael Meurer finds that communications and computer technology patents are likely to provide a net *dis*incentive for innovation because the risk of patent litigation for public software firms surpasses the profits derived from these patents. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 144 (2008).

Of course, without information about the underlying quality of patent applications, grant rates tell us little about either the quality of patents the PTO is issuing or the "correctness" of the patentability standards that examiners are using. Nonetheless, the extent to which the PTO is looking to augment its budget by taking an expansive view on substantive patent law is likely to manifest in an industry-specific manner.[135] As Dan Burk and Mark Lemley have persuasively argued, patent doctrine is not transsubstantive as it may first appear, but instead is industry-specific and largely shaped by the disciplines to which it is applied.[136] The PTO would develop its views on patent law so that examiners are generally instructed to follow patentability standards that are more expansive than non-biased standards (the standards influenced by only the public interest) in an effort to grant more patents. Yet, as the above analysis suggests, the magnitude of the bias would be greatest in technological fields where the PTO stands to financially benefit the most from granting patents—such as semiconductors and electrical devices, communications and computer technology—and the smallest in sectors

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[135] The PTO is likely to be influenced by not only the revenue it collects per average patent granted in a technology field but also the average cost to the PTO to examine a patent application within that technology field. For example, if the average semiconductor patent cost the PTO $100,000 to examine, then the agency would have little financial incentive to grant more patents in this field because even with high renewal rates, the PTO would fail to collect enough revenue to cover its costs of examination. It is, however, difficult to estimate the average cost to the Agency to examine a patent application as a function of technology. There are a number of factors that will contribute to the expenses the Agency incurs when examining a patent, including the percentage of applications that are continuations and the complexity of the technological field. The former suggests that both semiconductor and computer technology patent applications are less expensive for the PTO to examine than biotechnology and pharmaceutical patent applications. *See* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 86 tbl.2 (2004) (finding that the frequency of continuation practice varies across technological fields with a high percentage (43%) of continuations filed in the biotechnology field and lower percentages (25% and 18%, respectively) of continuations filed in computer technology and semiconductor technology). The complexity of the technology also plays an important role in contributing to the costs the Agency must bear in examining patent applications. While the hours an examiner is given to evaluate a patent application varies depending on the complexity level of the art—the most complex areas are allotted 31.6 hours per application whereas the least complex areas are allotted 13.8 hours per application—the PTO has not fully disclosed these hour requirements. E-mail from David Wiley, Acting Dir., Office of Planning & Budget, U.S. Patent & Trademark Office, to author (Sept. 23, 2010, 2:50 PM) (on file with author).

[136] BURK & LEMLEY, *supra* note 35, at 169–70. *See generally* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575 (2003).

where the PTO stands to financially benefit the least from granting patents—such as biotechnology or pharmaceuticals.[137]

C. *Administrative Concerns*

This subpart explores whether the PTO's tendency to develop and interpret substantive patent law in an expansive manner is tempered or even entirely counteracted by administrability concerns. The PTO may take a more restrictive stance on substantive standards for at least two reasons related to administrative issues. First, the PTO may resist extending patent rights to an emerging field of technology because the Agency lacks either a staff with significant knowledge in this technology or the resources necessary to review patent applications in this emerging field.[138] Second, the PTO may interpret and develop the law in a restrictive manner in hopes of decreasing its backlog of 735,000 patent applications.[139] The backlog of patent applications is a pressing issue to the Agency; the PTO may hope that taking a restrictive stance on patentability standards will result in the filing of fewer patent applications.

While the PTO's efforts to administer the patentability standards may lead the PTO to take a more restrictive stance on substantive patent law issues, the frequency is likely much smaller than it first appears. First, patent applications within an emerging field usually begin to trickle into the PTO over a few years. It is unusual for the Agency to see large jumps in the filing of patent applications in an emerging field within a few years, even without a

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[137] It is possible that pharmaceutical patents are just financial losers to the PTO and that the Agency actually takes too restrictive a stance on patentability standards in this area in order to decrease patent filings in this field. This would be particularly troublesome from a social welfare perspective, as patents on pharmaceuticals are generally believed to incentivize investment in socially valuable innovation. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 504 (2009) ("It is widely accepted that patents play an essential role in motivating private investment in pharmaceutical R&D, and those investments have yielded tremendous social gains through the resulting introduction of new drugs.").

[138] *See* Diamond v. Diehr, 450 U.S. 175, 218 (1981) (Stevens, J., dissenting) ("No doubt [the PTO] may have been motivated by a concern about the ability of the Patent Office to process effectively the flood of applications that would inevitably flow from a decision that computer programs are patentable.").

[139] PERFORMANCE AND ACCOUNTABILITY REPORT, *supra* note 38, at 114 tbl.3. *See* U.S. PATENT & TRADEMARK OFFICE, 2007–2012 STRATEGIC PLAN 1 (2007), *available at* http://www.uspto.gov/web/offices/com/strat2007/stratplan2007-2012.pdf (noting the number one goal stated in the PTO's Strategic Plan includes optimizing patent timeliness).

court opinion that changes the default rules.[140] The large turnover rate of examiners allows the PTO to continually infuse the Agency with examiners fresh from the field. Much emerging technology builds on present day scientific expertise or the further development of an existing field; thus the PTO will usually already have some personnel with significant experience in the field.[141] Furthermore, not all restrictive stances on the law will result in decreasing the number of patent applications that are filed and hence reduce the PTO's backlog. Patent attorneys and patent applicants have become very clever at crafting claim language to get around substantive patent law restrictions.[142] Thus, if the PTO takes a restrictive stance on patentability standards, it may result in a shift of the types of patent applications the PTO receives but will not decrease the total number of applications.

Finally, there are a variety of policy levers, which the PTO can utilize, that could conceivably decrease the PTO's backlog without exposing itself to reversal by the Federal Circuit and the costs associated with defending its actions in court.[143] To this end, the PTO has recently announced the "Patent Application Backlog Reduction Stimulus Plan," under which an individual, small firm, or other enterprise that qualifies as a "small entity" can choose to abandon a previously filed application that has not been examined in

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[140] This assumes that the effort it takes the PTO to examine a patent application corresponds with the number of applications filed. An exception to this rule is expressed sequence tags (EST), or fragments of DNA. Although the PTO had only received about 100 large DNA patent applications up to 1996, they contained as many as 500,000 EST. *See* Eliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCIENCE 643, 643 (1996) (PTO arguing that it would take the Agency close to a hundred years and 20 million dollars to examine the pending patent applications). Thus, it was not too surprising that the PTO took a restrictive stance, requiring that a patent applicant must know the underlying gene function of the EST in order for the utility standard to be satisfied. *In re* Fisher, 421 F.3d 1365, 1368–69 (Fed. Cir. 2005).

[141] For example, the field of biotechnology has offered a host of interesting patentability questions, including genes, expressed sequence tags, antibodies, and genetic testing.

[142] *See, e.g.*, Dennis Crouch, Bilski*: Adding Obvious But Meaningful Limitations*, PATENTLY-O (Nov. 3, 2008, 11:46 AM), *available at* http://www.patentlyo.com/patent/2008/11/bilski-adding-o.html (noting that claim drafting techniques can be used to satisfy restrictions in substantive law without "sacrificing valuable claim scope").

[143] While the PTO does not "tally the number of attorney hours devoted to any single project," *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), a case where the PTO arguably took a more restrictive stance on patentable subject matter was "certainly a whopper" in terms of man power to defend in court. E-mail from Raymond Chen, Deputy General Counsel for Intellectual Prop. Law & Solicitor, to author (July 5, 2010, 10:07 PM) (on file with author).

exchange for the expedited review of another patent application.[144] Further, the PTO is seeking comments on adopting deferred examination, where PTO examiners would no longer automatically review every patent application that is filed but instead would only review patent applications wherein the applicants submitted a specific request for examination. Deferred examination systems are employed in many patent-granting countries,[145] and these jurisdictions have reported that a substantial number of patent applicants have never requested substantive examination.[146]

Yet even if we assume that the PTO's incentive to skew its views of substantive patent law is offset by other institutional concerns such as patent backlog, it remains imperative that we endeavor to understand any distortion in the law caused by the unidirectional review of PTO decisions and the financial pressures to grant patents. This is particularly important when the offsetting biases are only temporary in nature. If and when the PTO decreases its backlog, this potential counter-bias will be gone. The asymmetric review of PTO determinations and financial incentives to grant patents will, however, still remain, and hence it is likely that these biases will win out over the long term.

IV. EXAMINER INCENTIVES AND PATENT LAW DEVELOPMENT

The previous Part identified two asymmetric incentives that are likely to be internalized by high-level officials within the PTO—i.e., the officials that are setting the Agency's views on substantive patent law—and explained why these incentives exert an expansionary pressure on the PTO's views on substantive law. Up until this point, this Article has argued high-level officials articulate the Agency's patent protective standards through guidance documents and BPAI decisions and that patent examiners readily follow the Agency's views. However, high-level officials can influence the

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[144] *See* Perry E. Van Over, *A New Pilot Program: Patent Application Backlog Reduction Stimulus Plan*, ORTHOPRENEUR, Mar.-Apr. 2010, 36, 36. As small entities pay half the fees of other patent applicants, it is not surprising that the PTO targeted these backlogged patent applications.

[145] *See* Letter from Alan Hammond, Chief Intellectual Prop. Counsel, Life Techs., to the Honorable John J. Doll, Acting Dir. of the U.S. Patent & Trademark Office (Feb. 26, 2009), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/comments/deferredcomments/lifetechcorp.pdf (noting that all of the top ten trading partners of the United States, with the exception of Mexico, currently employ deferred examination).

[146] For example, the Japan Patent Office (JPO) currently operates under a three-year period of deferral. In 2008, the JPO reported that only 65.6% of all applications proceeded to examination. THE TRILATERAL OFFICES, FOUR OFFICES STATISTICAL REPORT 52 (2008), *available at* http://www.trilateral.net/statistics/tsr/statisticsreport.html.

development of substantive patent law beyond instructing examiners to apply the Agency's views on patent law. This Part explores how PTO officials may use other channels, most likely in tandem with guidance documents and BPAI decisions explored in Part II, to push substantive patent law standards in a patent-protective direction. More specifically, this Part explores how the PTO structures examiner incentives to exert expansionary pressure on substantive patent law.

In general, there is widespread agreement that the incentive structure of examiners is biased towards the allowance of patents.[147] For example, the longstanding PTO policy requiring examiners to articulate the reasons for rejecting patent claims but not for allowing patent claims means that examiners often have to work harder to reject rather than to allow a patent application.[148] This one-sided workload may bias examiners towards allowing patents, especially in close cases. Further, it is well recognized that the examiner's compensation system also favors allowance.[149] Examiners are

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[147] There are also at least two other reasons why examiners may struggle to reject invalid patents: the ex parte nature of the administrative process for obtaining a patent and the fact that the burden of proof is on the examiner to show that a patent should not issue. However, these reasons are less clearly in the control of high-level officials in the Agency. Finally, it should be noted that the unidirectional review of examiner decisions by the BPAI further buttresses any patent-protective views of the Agency. A patent applicant can only seek court review of a patent denial after she has exhausted her administrative remedies—when both the examiner and the BPAI have rejected the patent application. Because the BPAI only reviews patent applications that have been denied by an examiner, the BPAI can only correct erroneously denied patents. Therefore, BPAI review affects the distribution of patent decisions in a one-way manner—it eliminates some of the erroneously denied patents and concomitantly decreases the risk of PTO reversal. *See* Benjamin & Rai, *supra* note 16, at 316–17 (arguing that the Federal Circuit should be more deferential to PTO decision making with respect to patent denials than to patent grants, in part because BPAI review of patent denials is likely to result in the PTO's denying invalid patents).

[148] *See* Lemley, *supra* note 76, at 1496 n.3 ("[E]xaminers must write up reasons for rejection, but not reasons for allowance, giving them more incentives to allow rather than reject an application."); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 324–25 (2001) ("Patent Office practice requires that examiners articulate their reasons for a rejection, while most often examiners need say nothing if they chose to allow a case. The belief is widely held that this regime encourages examiners to allow rather than to reject applications.").

[149] *See, e.g.*, THOMAS H. STANTON ET AL., NAT'L ACAD. OF PUBLIC ADMIN., U.S. PATENT & TRADEMARK OFFICE: TRANSFORMING TO MEET THE CHALLENGES OF THE 21ST CENTURY 102 (2005) (noting that the productivity schedule is "highly biased toward early allowances"); Long, *supra* note 19, at 1991 ("Internal PTO practices create a bias in favor of granting patents."); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14

rewarded by the number of patent applications they can dispose of, and the fastest and easiest way to dispose of a patent application is to allow it. The PTO's recent revision to the examiner compensation system reduces the incentive to grant patents but does not eliminate it altogether.[150] Both the compensation system of examiners and PTO policy to require examiners to provide written explanation for why they reject but not allow a case are within the control of the Agency. However, PTO officials have never proposed that examiners should also provide a written explanation for why a patent is allowable, and the recent revision of the compensation system, which provided a chance to completely recalibrate examiners incentives, instead left in place a bias towards allowance. Thus, it is possible that the asymmetric incentives discussed in Part III may also be manifesting in the Agency's decision to continue structuring examiner incentives to favor patent grants.

In addition to reinforcing the pro-patentee official views of the PTO, examiner incentives can also set de facto official views of substantive patent law in areas where examiners have not been provided with Agency guidance. It is highly unlikely that an individual examiner's substantive rule will be applied uniformly across patent applications—examiners simply lack the ability to communicate with, and exert influence upon, a substantial number

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BERKELEY TECH. L.J. 577, 607 (1999) ("Consequently, the only way to earn bonus points with confidence is to allow a patent application."); Thomas, *supra* note 148, at 324–25.

[150] Press Release, USPTO, USPTO Joint Labor-Management Task Force Proposes Significant Changes to Examiner Count System (Sept. 30, 2009), *available at* http://www.uspto.gov/web/offices/com/speeches/09-19.htm. The old compensation system gave examiners credits for only two actions: first action on the merits and disposals. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF COMMERCE, USPTO SHOULD REASSESS HOW EXAMINER GOALS, PERFORMANCE APPRAISAL PLANS, AND THE AWARD SYSTEM STIMULATE AND REWARD EXAMINER PRODUCTION 7–8 (2004). A first action on the merits credit is earned when an examiner makes initial written communication to the applicant as to the patentability of the claimed invention. *Id.* at 7 n.7. A disposal credit is generally earned when an application is allowed or abandoned. *Id.* at 7 n.8. Absent from the ways of earning a disposal credit is the continued rejection of an application or a new rejection based on the applicant's response to the first office action on the merits. STANTON ET AL., *supra* note 149, at 103.

The new metric of evaluation improves on the old system in several ways. First, examiners earn credits for final rejections. Press Release, USPTO, USPTO Joint Labor and Management Count System Task Force Proposal, Update to the Examining Corps (Sept. 30, 2009), *available at* http://www.uspto.gov/web/offices/ac/ahrpa/opa/documents/briefing_for_corps-final_draft-093009-external-jrb.pdf. Second, actions are now weighted—an examiner now earns more credits for a first action on the merits and less for a disposal. *Id.* To the extent that the old system skewed examiner incentives, the new system is an improvement and should encourage more neutral decision making.

of their counterparts. Because examiner incentives favor allowance, individual examiners all facing the same close legal question may simply grant the patent. In this way, examiners who have not been given guidance from high-level officials may, acting individually, de facto set the PTO's stance on a substantive law.

V. EXPANSIONARY PRESSURE ON THE FEDERAL CIRCUIT

This Article has thus far focused almost exclusively on the PTO. The previous Parts first showed that the PTO must develop its own views of substantive patent law, and second, identified a bias that pushes the PTO's views on substantive patent law in a patent-protective direction. The PTO's tendency to expand the patentability standards, while of concern in its own right, could conceivably be corrected by the Federal Circuit. In theory, the appellate court could continually cut back on the PTO's expansive views of patent law. Yet, this Part argues the Federal Circuit is unlikely to do so. Specifically, this Part explores how the PTO's overly permissive views of substantive patent law in turn create pressure for the Federal Circuit to enunciate legal standards that, over time, also drift in the expansive direction.

To begin, overly expansive patentability standards can have negative ramifications on consumers and innovators. While patents promote the production of new inventions by giving inventors a monetary incentive to devote resources to the creation and development of an invention, they do so at a cost to consumers—higher prices and less access to the invention during the duration of the patent.[151] If patents become too plentiful or if patent rules become too strong, the costs of patents may cease to outweigh the benefits to consumers.

Patents, however, also give rise to dynamic costs. While patents promote innovation, they also limit the productive uses of the patented inventions, such as the use of the invention for further improvement or the use of the invention as inputs to future innovation.[152] Innovation is highly

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[151] *See* DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW: CASES AND MATERIALS 6 (1998); MERGES & DUFFY, *supra* note 13, at 253–56 (describing the incentive systems meant to drive patent law); Michael Abramowicz, *The Uneasy Case for Patent Races Over Auctions*, 60 STAN. L. REV. 803, 809–10 (2007) (assessing whether patent auctions can be structured to benefit the social welfare).

[152] *See* F. M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 450–53 (2d ed. 1980); S. SUBCOMM. ON PATENTS, TRADEMARKS, & COPYRIGHTS OF THE S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM 21 (Comm. Print 1958) (Fritz Machlup). Crafting substantive patent law requires a balance between property rights and the public domain, which has long been recognized in the central statutory doctrines of patentability. Although the utility

cumulative.[153] For example, basic technology forms the basis for a variety of applications in multiple technological fields; follow-on inventions can improve the original discovery; and an invention can serve as a research tool in the development of downstream inventions. Overly broad patentability standards, especially those that result in the patenting of inventions that either would have been developed without a patent or result in the issuance of patents on inventions that are already in the public domain, result in chilling follow-on research and development, and are likely to decrease overall social welfare.[154]

Following the above exposition on why overly expansive patentability standards are undesirable, subparts A and B examine why the Federal Circuit is likely to entrench the PTO's expansive take on substantive patent law. Subpart C then discusses the likelihood that other legal actors in the patent system will offset or correct an unwarranted evolution of substantive patent law.

A. *Lock-In Effect*

Once the PTO begins determining patentability based on an expansive rule, a susceptibility to lock-in may arise. The patent system is specifically designed to encourage investment in innovation that is supposed to return yields over the twenty-year term of the patent grant. Once an industry has developed around a particular rule, the Federal Circuit may be concerned with disrupting business investments and patent strategies created on the reliance of thousands of patents issued by the PTO.[155] This may lead the

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standard requires that in order to be patentable an invention must be useful, the Supreme Court has stressed that allowing a patent on an invention whose use is yet to be known "may confer power to block off whole areas of scientific development, without compensating benefit to the public." Brenner v. Manson, 383 U.S. 519, 534 (1966). Further, the patentable subject matter requirement has a broad scope, but it does not include phenomena of nature or abstract scientific principles, as the Supreme Court has emphasized that the exclusion of these abstract scientific principles and phenomena of nature allows these "basic tools" of science and technology to be available for all scientists to draw upon. *See* Gottschalk v. Benson, 409 U.S. 63, 67, 71–72 (1972).

[153] *See generally* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP., Winter 1991, 29, 29.

[154] *See supra* note 11.

[155] The Supreme Court has shown concern for disrupting "the settled expectations of the inventing community" in several opinions. *See, e.g.*, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 739 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community."); *see also* NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION,

Federal Circuit to entrench the PTO's expansionary views on substantive patent law even if the court believes that the PTO's substantive standard is suboptimal.

The propensity for lock-in increases if the Federal Circuit is not given, in a timely manner, the opportunity to consider whether the PTO's expansive views on substantive law are desirable. The longer the time lag between the PTO's implementation of its views and the Federal Circuit's opportunity to review the Agency's viewpoints, the greater the chances for lock-in. There are several reasons why the Federal Circuit may have limited opportunities to revisit the PTO's expansive standard. First, the asymmetric review of PTO determinations means that the Federal Circuit cannot immediately review a pro-patentee substantive rule. Instead, the Federal Circuit can only review a pro-patentee legal rule once the erroneously granted patents have been asserted during patent litigation and also make their way through prolonged district court litigation. This process, on average, can take close to a decade.

Second, certain legal doctrines are infrequently litigated during patent infringement suits or declaratory judgment actions. For example, a recent study of litigated patent cases revealed that a lack of patentable subject matter accounted for only 0.7% of the invalid patents.[156] The majority of developments of this doctrine come from Federal Circuit review of patent denials, not patent grants.[157] The dearth of opinions stemming from patent litigation addressing patentable subject matter has a negative feedback effect—the PTO is likely to exercise substantial discretion with respect to patentable subject matter doctrine because of the lack of guidance from the Federal Circuit. While the Federal Circuit could attempt to fill this legal void by considering the issue of patentable subject matter sua sponte,[158] the

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AND PUBLIC HEALTH 101 (2006) (estimating that over 33,000 DNA-related patents have been granted).

[156] Allison & Lemley, *supra* note 12, at 208 tbl.1 (the most routinely asserted grounds are obviousness (42.0%) and novelty (31.1%)). For an excellent discussion on why litigants may shy away from asserting patentable subject matter as a ground for invalidating a patent, see Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN'S L. REV. 519, 528–29 (2006).

[157] Allison & Lemley, *supra* note 12, at 203 (noting that patentable subject matter cases "are more likely to arise in appeals from the PTO than in normal litigation"); John R. Allison & Mark A. Lemley, *How Federal Circuit Judges Vote in Patent Validity Cases*, 27 FLA. ST. U. L. REV. 745, 748 (1999) (noting a "subject matter bias introduced" into their dataset of litigated patents by "excluding appeals from the PTO").

[158] Most recently, the panel of judges did so in *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007), a case involving the patentability of a process for ensuring that disputes relating to legal documents, such as wills or contracts, are resolved through arbitration.

appellate court is unlikely to routinely do so as several Federal Circuit judges have expressed their disapproval of such action.[159]

Third, the Federal Circuit may not be given the opportunity to review the PTO's expansive views on substantive patent law even if the substantive standard is frequently asserted during patent litigation. The majority of patent litigation is between companies that hold patents in the same or closely related technological fields.[160] Once an industry has adapted to a specific legal rule, it may be more likely to favor its continuance,[161] as transitioning to a new legal regime is costly. Thus, accused patent infringers may be less inclined to make arguments that affect broad swaths of patent rights as they may fear that such a challenge would also call into question the validity of

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[159] *See In re* Comiskey, No. 2006-1286, 2009 U.S. App. LEXIS 400, at *12–13 (Fed. Cir. Jan. 13, 2006) (Moore, J., Newman, J., and Rader, J., dissenting). Although *In re Comiskey* cited the Supreme Court case, *SEC v. Chenery Corp.*, 318 U.S. 80 (1943), for the proposition that it is proper for the court to consider new issues not relied upon by the Agency, 499 F.3d at 1372, *In re Daneshvar* cited *Chenery* for the proposition that "we are limited to reviewing the grounds relied on by the agency." No. 2009-1475, 2010 U.S. App. LEXIS 3149, at *5 (Fed. Cir. Feb. 18, 2010). There are, of course, good public policy reasons why courts do not routinely consider issues sua sponte. Courts benefit from the parties developing the record, doing thorough legal research, and responding to each other's legal arguments. The workload of judges limits their ability to conduct routinely thorough research on issues that were not briefed. Even beyond judicial economy arguments, fundamental fairness to the parties also weighs against judges considering issues sua sponte. *See In re* Lee, 277 F.3d 1338, 1345–46 (Fed. Cir. 2002) ("Consideration by the appellate tribunal of new agency justifications deprives the aggrieved party of a fair opportunity to support its position; thus review of an administrative decision must be made on the grounds relied on by the agency."); *In re* Margolis, 785 F.2d 1029, 1032 (Fed. Cir. 1986) ("In the interest of an orderly and fair administrative process, it is inappropriate for this court to consider rejections that had not been considered by or relied upon by the Board."). *See generally* Barry A. Miller, *Sua Sponte Appellate Rulings: When Courts Deprive Litigants of an Opportunity to Be Heard*, 39 SAN DIEGO L. REV. 1253 (2002).

[160] There is a growing contingency of litigation involving non-practicing entities. However, because these entities do not sell any commercial products, they are unlikely to ever be sued by a patent holder. As such, they have almost no incentive to cut back on expansive patent law doctrine.

[161] Consider the example of the pharmaceutical industry, which relies heavily on patent protection to recoup the research and development costs of developing drugs. This industry often makes determinations about which compound to seek FDA approval of ten to fifteen years before the commercial product will come to market. The patentability of the compound factors heavily into the companies' decisions on whether or not to pursue FDA approval of a compound. Thus, the pharmaceutical industry has strong preferences to minimize changes to the law, as changes to the law may jeopardize their ability to secure patents and the validity of the patents they have already obtained.

their own patents.[162] At least one scholar has argued that this is a reason why patentable subject matter is not more frequently asserted during patent litigation.[163] If a patent is invalidated on the basis of patentable subject matter, it is likely that a number of other patents that are not involved in the litigation will also be rendered invalid by the decision.

Take, for example, gene patents. Despite the prolonged and intense public debate regarding the patenting of genes[164] and the fact that the PTO has been issuing gene patents for over twenty-five years,[165] a court only recently considered whether DNA gene sequences, particularly the so-called

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[162] *Cf.* Rai, *supra* note 4, at 1075 ("Although patent bar members represent both patent plaintiffs and patent defendants, both plaintiffs and defendants are often patent holders. Thus, while a patent lawyer may attack the particular patents held by her opponent, she is unlikely to make more sweeping legal and policy arguments that emphasize the problems caused by strong, or numerous, patents.").

[163] *See* Kane, *supra* note 45, at 726. *But see* Golden, *supra* note 5, at 683–84 (arguing that patent holders are more frequently arguing for stricter definitions of patentable subject matter as amicus curiae). However, these arguments appear to be limited to amicus curiae at this point. Importantly, the majority of recent cases before the Federal Circuit asserting patentable subject matter have been patent denials (i.e., the PTO, not patent holders, was arguing that the invention in question did not constitute patentable subject matter). *See In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc) (holding that patentable processes must be tied to a machine or impart a physical transformation); ."); *In re* Nuijten, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (holding that a "transitory, propagating signal . . . cannot be patentable subject matter"); *In re* Comiskey, 499 F.3d at 1378 ("[T]he present statute does not allow patents to be issued on particular business systems—such as a particular type of arbitration—that depend entirely on the use of mental processes.").

[164] For a general discussion of the debate regarding gene patents, see Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 305–09 (2002); Leon R. Kass, *Triumph or Tragedy? The Moral Meaning of Genetic Technology*, 45 AM. J. JURIS. 1 (2000); Pilar N. Ossorio, *The Human Genome As Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425 (2007).

[165] The PTO has made it clear that it believes genes are patentable. *See* Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) ("An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound."); *see, e.g.*, U.S. Patent No. 4,703,008 (filed Nov. 30, 1984) (issued Oct. 27, 1987) (regarding DNA sequences encoding erythropoietin); U.S. Patent No. 4,431,740 (filed June 8, 1982) (issued Feb. 14, 1984) (regarding vectors for human insulin genes).

breast cancer genes, constitute patentable subject matter.[166] Noticeably, the parties that filed the lawsuit arguing that gene patents are not patentable subject matter are not entities that own patents in the biotechnology field but are instead the American Civil Liberties Union and the Public Patent Foundation.[167] While the district court invalidated the claims to "isolated and purified" genes on the basis that genes did not constitute patentable subject matter, most scholars believe it is unlikely that the Federal Circuit or the Supreme Court will remove gene patents entirely from the patent system because of settled expectations—the PTO has issued over tens of thousands of gene patents and the biotechnology industry has operated under the assumption that genes constitute patentable subject matter for close to a quarter century.[168]

B. *Skewed Distribution and Asymmetric Review*

While the previous subpart explored why the Federal Circuit may knowingly entrench the PTO's patent-protective views on substantive patent law, this subpart examines how the asymmetric review of PTO decisions, along with biased PTO decision making, is likely to result in the Federal Circuit unknowingly enunciating expansive legal standards.[169]

Most obviously, the Federal Circuit will not always arrive at the correct decision; the appellate court will, at times, err in deciding cases.[170] However,

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[166] Judge Sweet of the Southern District of New York held that "isolated and purified" genes did not constitute patentable subject matter. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 232 (S.D.N.Y. 2010). This case is currently on appeal before the Federal Circuit.

[167] American Civil Liberties Union and Public Patent Foundation filed the lawsuit on behalf of researchers, genetic counselors, women patients, cancer survivors, breast cancer and women's health groups, and scientific associations representing 150,000 genetics, pathologists, and laboratory professionals. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 183, 186–89.

[168] *See, e.g.*, Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, and Drug Development*, 53 UCLA L. REV. 871, 892 (2006).

[169] Jonathan Masur also explores how the skewed distribution of cases in patent denials may lead the Federal Circuit to expand substantive patent law. He appears to limit his analysis to when random Federal Circuit error or deviations in panel make-up will lead the court to overturn an invalid patent denial. Masur, *supra* note 17. In addition, I explore how the evaluative and decisional process of Federal Circuit decision making can be affected by skewed distribution of cases in patent denials, also leading the court to expand substantive patent law standards.

[170] The sources of potential error are beyond the scope of this paper but could be the result of the court misconstruing the technology at issue or could be the result of the PTO

the skewed distribution of patent denials means that Federal Circuit error is more likely to result in the unwarranted expansion than the unwarranted restriction of legal doctrine.[171] If the PTO's views on substantive patent law were guided purely by its mission statement, the Agency would instruct its examiners to use the non-biased standard. Even under non-biased PTO decision making, the distribution of patent denials contains many more invalid than valid patents, as the inventions at issue in patent denials have already been screened for patentability by both patent examiners and the BPAI. The tendency of the PTO to take an expansionary view of substantive patent law will further skew the distribution of patent denials above the non-biased standard. Since the PTO has interpreted and developed substantive law in a patent-protective direction, the overwhelming majority of patents that are denied by the Agency, even erroneously, are invalid (above the non-biased standard). Assuming that the Federal Circuit is itself unbiased and likely to err equally along the continuum of cases appealed before it (except at the extremes), the highly skewed distribution of patent denials before the Federal Circuit means that appellate court error is likely to result in the erroneous reversal of a patent denial (the unjustified expansion of legal doctrine) rather than the erroneous affirmation of a patent denial (unwarranted restriction of legal doctrine).

Along the same vein, the Federal Circuit's decisional process may be affected by the unidirectional review of PTO determinations. Because the distribution of patent denials on appeal contains many more invalid than valid patents, the appellate court should overwhelmingly affirm the PTO. Yet the Federal Circuit may find it challenging to reverse the PTO only at a rate that corresponds with Agency error, as all that is being asked of the court is to find fault in PTO decision making. Every patent denial involves a case in which the patent applicant is asserting that the PTO erroneously denied patent protection—that the PTO defined the patentability standards too

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lawyers not clearly presenting the legal issues at hand. *See* Nard & Duffy, *supra* note 7, at 1632 (suggesting that appellate court error could stem from one-sided poor representation); Rai, *supra* note 4, at 1053–54 (arguing that the Federal Circuit erred on a factual question due to lack of technical expertise and turned this factual error into a generalizable legal principle).

[171] Of course, Federal Circuit error will not always produce a shift in the scope of the legal doctrines. Sometimes Federal Circuit error may affect only the outcome of the case at issue. However, even when the Federal Circuit errs only on factual determinations, it may also affect the legal standards. *See* Rai, *supra* note 4, at 1053–54 (arguing that the Federal Circuit erred on a factual question due to lack of technical expertise and turned this factual error into a generalizable legal principle).

restrictively.[172] As such, the Federal Circuit is under one-way demands to implement patentability standards that favor patent applicants (i.e., are expansive in nature).[173] With doctrines that are rarely litigated outside of the PTO context, the Federal Circuit is not being asked to do the opposite—to restrict the scope of the substantive standards. Thus, with respect to patent denials, the Federal Circuit is under systematic pressure to shift the patentability standards in a patent-protective direction.

Regardless of whether the Federal Circuit expands or restricts legal doctrine, the appellate court may have the opportunity to revisit its decision in the future. Yet, the nature of the asymmetric review process is likely to result in the Federal Circuit more frequently revisiting its decisions that restrict, when compared with those that expand the law, especially for doctrines that are rarely asserted during patent litigation. The resulting outcome of this process is that the law will be further pushed in the expansionary direction. Imagine, for example, that the Federal Circuit decides to substantially restrict the scope of patentable subject matter by holding that methods of gene testing, such as the tests that identify BRCA1 and BRCA2 breast and ovarian cancer susceptibility genes, are unpatentable. Diagnostic companies who have had their patent denied by the PTO's implementation of the new standard may appeal the decision to the Federal Circuit, arguing that the court's holding is too broad and that at least a subset of inventions that fall under the umbrella of the new standard, such as methods of gene testing that have a therapeutic effect on the patients, should remain patentable. These appeals provide the Federal Circuit with

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[172] Of course, the patent applicant could appeal a large range of issues that are not limited to substantive patent law issues but also include factual errors or procedural issues. For example, the patent applicant may argue that the PTO erred in what a prior art reference disclosed. This is a question of fact. *In re* Napier, 55 F.3d 610, 613 (Fed. Cir. 1995). Conversely, a patent applicant could argue that the PTO made a procedural error. *See, e.g.*, 35 U.S.C. § 185 (2006) (prohibiting the grant of a patent to a person who has filed a foreign patent application and failed to obtain a required license from the PTO).

[173] This point has been made with respect to the asymmetric reviewability of criminal law issues. In criminal law, the government is barred from seeking appeal of a number of adverse rulings. In contrast, the criminal defendant has strong incentives to appeal adverse rulings. *See* Ian R. Macneil, *A View from the South*, 7 CAN. BUS. L.J. 426, 437–38 (1982) ("[The limited ability of the government to appeal adverse criminal law rulings] results in an imbalance whereby reviewing courts are under steady, relatively one-way demands to change or implement criminal law in directions favouring the criminal defendant. . . . It is difficult to believe that over a period of time this leaves the substance of legal development unaffected.").

opportunities to reconsider its decision or at least limit its reach.[174] In contrast, imagine that the Federal Circuit substantially enlarges the scope of patentable subject matter by holding that methods of gene testing are patentable. Because patent grants are not subject to immediate judicial review and the doctrine of patentable subject matter is not frequently asserted during patent litigation, the court may not be asked to reconsider or limit its decision. In fact, the Federal Circuit is likely to be asked to do the exact opposite. The majority of appeals raising the issue of patentable subject matter will likely be patent applicants who have had their patent denied under the new standard and will be urging the court to push the standard in an even further expansive direction, such as to also allow for expansive patenting of business methods. As such, the dynamic effect of the asymmetric review of PTO determinations creates an additional pressure on the Federal Circuit to expand the scope of the patentability requirements.

C. *Congress and the Supreme Court*

If the patentability standards continue to expand over time, institutional actors other than the PTO and the Federal Circuit may attempt to adjust them. As in other areas of federal law, an unwarranted expansion of legal doctrine may be corrected by statutory clarification or the Supreme Court. Yet there are specific characteristics of the patent system that limit the ability of both Congress and the highest Court to perform this function. Congress has stepped in from time to time to correct patent law standards that have gone astray.[175] However, Congress's last overhaul of the patent system was close to sixty years ago. Despite growing unrest with substantive patent law, recent congressional action in the patent arena, especially in comparison with other intellectual property areas such as copyright, has been limited.[176] In the last five years there have been a number of patent reform bills that have been introduced in Congress, but none have been passed. Stalled congressional action has largely been blamed on disagreement between the two major interest groups in patent law—the pharmaceutical industry and information/communication technology firms.[177]

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[174] *But see* Dreyfuss, *Pathological Patenting*, *supra* note 33, at 1570 (noting a "repeat-player disadvantage" whereby lawyers frequently appearing before the Federal Circuit may be reluctant to reargue issues out of concern for themselves or their clients being on the receiving end of court criticism).

[175] *See, e.g.*, Nard, *supra* note 4, at 68–77 (describing congressional action in patent law to correct jurisprudence that has gone awry).

[176] *See* Long, *supra* note 19, at 1966 & nn.1–2.

[177] BURK & LEMLEY, *supra* note 35, at 101 ("The pharmaceutical and biotechnology industries opposed virtually all elements of patent reform directed at

It may be more likely that the Supreme Court could play an active role in the correction of substantive patent law standards. The certiorari petition process allows the Court to stay abreast of the evolution of legal standards by lower courts while also giving the Court the freedom to pick and choose which legal issues it believes are ripe for review.[178] Yet, it is more difficult for the Court to recognize when patent law standards are in need of readjustment than when other legal standards have gone astray. The exclusive jurisdiction of the Federal Circuit over patent law claims limits the ability of the Supreme Court to rely on recent circuit splits as a signal of which legal issues are in need of review.[179] While lawyers attempt to make up for this deficiency by relying on aged Supreme Court opinions and appellate precedents that pre-date the Federal Circuit, it is difficult to be convincing with old case law.[180]

VI. SOLUTIONS

The previous Parts have determined that the PTO must develop its own views of substantive patent law, identified a patent-protective bias in these views, and explored why the Federal Circuit may entrench the PTO's overly permissive stance on substantive patent law. Congress has several tools at its disposal for countering or eliminating the PTO's expansive substantive patent law views resulting from the Agency's financial incentive to grant patents and the unidirectional review of its determinations. Here, subpart A examines the possibility of implementing symmetric review of PTO determinations, and subpart B explores potential solutions designed to curb the PTO's financial incentives to grant patents.

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abuse. . . . On the other side, the software, electronics, Internet, and telecommunications industries generally lined up behind reform, but expressed skepticism toward those few reforms the pharmaceutical industry supported . . . .").

[178] *See generally* Golden, *supra* note 5 (arguing that the U.S. Supreme Court should not be the final arbitrator of the law but should instead serve as a course-corrector to the Federal Circuit).

[179] Nard & Duffy, *supra* note 7, at 1644 (noting that Supreme Court intervention in patent law is difficult to obtain because of the lack of recent circuit splits). While the Court appears in part to make up for this deficiency by inviting the Department of Justice, through the Solicitor General of the United States, to file a brief analyzing the petition, this process is hardly a substitute for inter-circuit conflict. David C. Thompson & Melanie F. Wachtell, *An Empirical Analysis of Supreme Court Certiorari Petition Procedures: The Call for Response and the Call for the Views of the Solicitor General*, 16 GEO. MASON L. REV. 237, 281 (2009) (noting that the Supreme Court is more likely to call for the views of the Solicitor General in intellectual property cases).

[180] Dreyfuss, *Pathological Patenting*, *supra* note 33, at 1571.

A. *Symmetric Review of PTO Determinations*

Under the current system, PTO determinations are only subject to immediate judicial review when the PTO denies a patent. If the PTO grants a patent, its actions will go uncontested for many years, if ever. Because the PTO seeks to limit its litigation costs and chances of reversal, the Agency has an incentive to interpret, apply, and develop the law in a patent-protective direction. Congress could alter this dynamic and balance the Federal Circuit's review of PTO decisions by enacting an administrative proceeding that allows third parties to challenge the validity of granted patents on the basis of all the patentability standards.[181] Importantly, the losing party (either the patent holder or a third party challenger) of a post-grant review proceeding must be able to appeal the PTO's decision to the Federal Circuit.[182] In this way, aggrieved parties can immediately appeal PTO decisions to either grant or deny a patent.

Balanced judicial review would constrain the PTO, especially in areas where the Agency has substantial discretion. As there is then less incentive to take an expansive view on substantive issues, the Agency will be less likely to fill legal voids with patent-protective rules. Furthermore, doctrines such as patentable subject matter, which are not frequently asserted during patent infringement suits, would benefit from further court development, as third parties utilize the post-grant system to force greater clarity in the law. Pressure on the Federal Circuit to expand substantive law would also wane. The distribution of patent denials would be less skewed towards invalid patents, as the PTO examiners will no longer be using overly permissive standards to determine patentability. A controversial decision by the PTO to expand patent law will be challenged more quickly, limiting the chances for

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[181] This includes novelty, nonobviousness, patentable subject matter, utility and the disclosure requirements. Jonathan Masur has also advocated for a third party challenge although he argues for a pre-grant system. *See* Masur, *supra* note 17.

[182] The PTO's post-grant decision should not be entitled to substantial deference. Giving deference to the PTO's legal determinations in post-grant decisions, when no such deference is afforded to the PTO's substantive patent law views in patent denials, is likely to result in exacerbating the Agency's tendency to interpret, apply, and develop substantive law in a patent-protective direction. If the PTO decides a close legal issue in favor of granting a patent, then a third party will challenge the validity of the granted patent in a post-grant review proceeding. The PTO will uphold the patent, as the patent was granted under the PTO's official standard, and the third party will appeal the decision to the Federal Circuit. The Federal Circuit will then be forced to give deference to the PTO's expansive legal standard. In contrast, if the PTO decides a close legal issue in favor of denying a patent, an aggrieved patent applicant will appeal the decision immediately to the Federal Circuit. The appellate court is in a better position to overrule the PTO, as no deference is afforded to the PTO's legal determinations in patent denials.

lock-in. Third parties will no longer have to wait to be subject to infringement action or meet the criteria to file a declaratory judgment action to oppose the validity of an expansive PTO rule, but can instead use the post-grant review system.[183]

While allowing members of the public to challenge the validity of granted patents on the basis of any substantive patent law standard will temper the PTO's expansionary bias, a post-grant review system must also guard against providing third parties—especially a patentee's competitors—too great an incentive to challenge issued patents. Without some sort of protection, competitors, especially larger businesses, could continually challenge the validity of their rivals' patents, creating a cloud of uncertainty around the patent. It is possible that such abuses could result in devaluing issued patents to the point that inventors may no longer have the incentive to partake in research and development. Thus, including cost-shifting provisions for irresponsible, or even malicious, actions could help to curb these potential abuses.

Fortunately, Congress could implement this post-grant review system with minor changes to existing law. Presently, third parties can challenge the validity of granted patents in a reexamination proceeding before the PTO.[184] While these proceedings are not frequently used, in part because only patents and printed publications that refute novelty and nonobviousness can serve as a basis for reexamination, they do provide the basic framework for the post-grant review system described in this Article. Congress could utilize the post-grant review system of trademarks at the PTO, and the post-grant patent review system in Europe, which has been in effect for nearly thirty years, as guidance for designing such a patent system in the United States.[185]

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[183] However, it is unlikely that all third parties will have standing before the Federal Circuit.

[184] The PTO has two procedures that provide a limited administrative procedure for reviewing granted patent applications, ex parte and inter partes reexamination. 35 U.S.C. §§ 301, 303 (2006). Both of these procedures suffer from having narrow substantive grounds for review and strict estoppel provisions. Thus, neither could possibly serve to balance the review of PTO determinations. Ex parte reexamination bars the participation of a third party once the PTO has determined whether a reexamination should commence. 37 C.F.R. § 1.550(g) (2010) ("The active participation of the *ex parte* reexamination requester ends with the reply pursuant to § 1.535, and no further submissions on behalf of the reexamination requester will be acknowledged or considered."). Inter partes reexamination allows for third party participation but in a limited manner—the third party has the right to file written comments addressing "issues raised by the Office action or the patent owner's response." 37 C.F.R. § 1.947 (2010). These problems have had a dramatic effect on the number of reexamination requests. *See supra* note 117.

[185] Several scholars have extensively explored design aspects of a post-grant opposition system. *See* MICHAEL A. CARRIER, INNOVATION FOR THE 21ST CENTURY,

B. *Eliminating the Financial Incentives to Expand Substantive Patent Law*

Presently, the PTO budget is set to the amount of its projected revenue from user fees. As a result, the PTO overwhelmingly garners its patent-operating budget through patent examination and post-allowance fees. However, the fee structure of the PTO is such that fees from patent examinations cover less than one-third of the Agency's cost for performing this service. In contrast, the post-allowance fees the PTO collects are pure profit—these services cost the PTO practically nothing. Thus, the PTO has strong financial incentives to grant patents and this incentive systematically pushes the Agency's views on substantive patent law in the patent-protective direction. Congress could eliminate or counter these financial pressures by either aligning the fees with the costs per service, funding the PTO from direct appropriations, or restructuring the fees at the PTO.

1. *Align Fees with Costs*

Congress could decrease the PTO's financial incentive to expand substantive patent law by aligning the actual costs of examination with the fees for the service.[186] The large disparity between examination fees and cost at the PTO is somewhat of an anomaly within patent systems. For example, the PTO's counterpart in Europe, the European Patent Office, charges over three times the amount that the PTO does to examine patent applications.[187] As the actual fees paid to the PTO for examination of a patent application are

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HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW 205–230 (2009); Mark D. Janis, *Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law*, 11 HARV. J.L. & TECH. 1, 93–117 (1997).

[186] Congress has recently considered giving the PTO fee-setting authority. Patent Reform Act of 2009, H.R. 1260, 111th Cong. § 11(a) (2009); Patent Reform Act of 2009, S. 515, 111th Cong. § 9(a) (2009). These patent reform bills include a provision that gives the PTO the ability to adjust fees based on their analysis of the costs of providing a service. Importantly, these bills also provide for oversight to the PTO fee-setting authority by requiring the process to include involvement by the public, the Patent Public Advisory Committee, and the House and Senate Judiciary Committees.

[187] The basic online filing fee is 105 euros, the search fee is 1,105 euros, and the examination fee is 1,480 euros. *See Schedule of Fees*, EPOLINE.ORG, http://www.epoline.org/portal/portal/default/epoline.Scheduleoffees;jsessionid=575E8222428724575C9301130FB4E5A0.jboss_portal_epoline_prod_1 (last visited Dec. 22, 2010). Using a conversion rate of 1.3669 dollars per euro, the total filing, search, and examination fee at the European Patent Office is $3,685. The PTO charges $1,090 for the same services.

a fraction of the overall cost of securing a patent,[188] modest increases to the examination fees should not have a significant, negative impact on patent filings.[189] The major drawback to this proposal is that the PTO's financial incentives to expand the standards of patentability will likely remain even when the disparity between examination cost and fees is extinguished. The PTO may still have an incentive to develop overly permissive views on substantive patent law because the PTO will still derive a substantial portion of its budget from post-allowance fees.

Beyond merely aligning the PTO's cost with its fees for examination, the fee structure of the PTO could be modified so that the Agency does not derive a substantial portion of its budget from post-allowance fees. Small changes—such as implementing additional pre-grant fees or restricting the amount of renewal fees the PTO can retain—could significantly decrease the PTO's financial incentives to grant patents. The largest drawback of restructuring the PTO fee schedule is that any fee structure involves balancing, not only the incentives of the PTO, but also of the patentees.[190] While it may be difficult to develop a fee schedule that optimizes both patent filers and Agency behavior, it is clear that there is ample room for improvement over the current system.

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[188] A utility patent application of minimal complexity costs on average $10,000 to prepare and prosecute while a utility patent application of relative complexity costs on average $16,000 to prepare and prosecute. AIPLA, REPORT OF ECONOMIC SURVEY 2009, at I-110–12 (2009).

[189] Recent studies have shown that, at least with respect to low patent fees, patent demand is relatively inelastic. *See* Timothy K. Wilson, *Patent Demand—A Simple Path to Patent Reform*, 2 INT'L IN-HOUSE COUNS. J. 806, 810–12 (2008) (arguing that filing fees need to be raised significantly in order to reach the elastic portion of the demand curve); Gaétan de Rassenfosse & Bruno van Pottelsberghe de la Potterie, *On the Price Elasticity of Demand for Patents* (European Ctr. for Advanced Research in Econ. & Statistics, Working Paper No. 2008-031 (2008)), *available at* http://econpapers.repec.org/paper/ecawpaper/2008_5F031.htm (finding that the demand for patents is responsive to price, but relatively inelastic).

[190] Most patent offices have some mix of pre- and post-grant fees. A mixture of high and low pre- and post-grant fees can be found in various national patent offices. For example, the United States and Switzerland have low renewal fees whereas Greece and Germany have relatively high renewal fees as the patents age. Gaétan de Rassenfosse & Bruno van Pottelsberghe, *The Role of Fees in Patent Systems: Theory and Evidence* 7 (European Ctr. for Advanced Research in Econ. & Statistics, Working Paper No. 2010-023 (2010)), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1694924.

2. *Partially Eliminate Self-Financing of the PTO*

In the end, the better option for eliminating the PTO's financial incentive to expand patentability requirements may be to fund the PTO, at least partially, from direct appropriations. If the PTO funding does not scale directly with its revenue collection, the Agency's financial incentive to interpret, apply, and develop substantive law in a patent-protective direction would be substantially curtailed.[191] There are other benefits to the elimination of the self-financing of the PTO. The most significant benefit is that it would force Congress to figure out how much money the PTO needs to provide its expected output and then fund the Agency accordingly. There is no reason to believe that the amount of money the PTO spends should be set to the amount of money that the PTO collects. Second, without having to consider how the fee-structure would skew the decision making of the PTO, Congress or the Agency itself could more easily experiment with the structure of patent fees. The historical belief that innovative activity is maximized by increasing the number of patent applications, which appears to be the reasoning underlying the current PTO fee-structure,[192] is no longer widely accepted.[193]

However, there may be concern that Congress would fail to adequately fund the Agency. The PTO's budget has grown over four-fold since it became funded on user fees. Even though the PTO is and remains chronically underfunded, Congress has, on several occasions, refused to increase PTO fees. To address this concern, the PTO could be partially funded though user fees and partially funded through direct appropriations. If the amount of money the PTO can collect through fees is capped, the Agency's financial incentives to grant patents should be tempered. Further, Congress may be more willing to adequately fund the Agency if only a portion of its budget is being directly appropriated.

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[191] To the extent that it costs the PTO more to deny than grant a patent, the PTO, if it wants to use resources for things other than reviewing patent applications, may still have a small financial incentive to grant patents.

[192] de Rassenfosse & van Pottelsberghe, *supra* note 190, at 3–4.

[193] There is growing evidence that patents are no longer used to protect innovation activity. Instead, patents are being used to prevent rivals from patenting related inventions, preventing suits and keeping one's own freedom to operate, enhancing one's own reputation as a successful innovator, or earning licensing revenues. *See generally* Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent?*, 23 BERKELEY TECH. L.J. 1063 (2008); Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* (Nat'l Bureau of Econ. Research, Working Paper No. 7552 (2000)), *available at* http://www.nber.org/papers/w7552.

VII. CONCLUSION

The PTO is largely thought to play a negligible role in the development of substantive patent law. The Agency lacks substantive rulemaking powers, and its legal determinations are afforded no formal deference by its reviewing court, the Federal Circuit. This Article argues that, nonetheless, the PTO has a substantial effect on the development of substantive patent law—one that exerts expansionary pressure on the contours of patent law. The Agency has inevitable discretion that requires it to develop its own views on substantive patent law. Yet, the PTO's relationship with the Federal Circuit and its financial incentives result in the PTO taking an overly permissive view on substantive patent law. Importantly, the PTO's patent-protective views of substantive patent law and the unidirectional review of the Agency's decisions in turn create pressure on the Federal Circuit to enunciate expansive legal standards.